PHOENIX
JANUARY 16-18, 2025

NRG Oncology

2025 WINTER MEETING
PHOENIX, AZ

NRG ONCOLOGY
2025 WINTER MEETING
Program Book

#NRG2025

Table of Contents

SESSIONS/SPECIAL EVENTS

WORKSHOP AGENDAS (CME/Non-CME)

INSTITUTIONAL ACCRUAL

ACKNOWELDGEMENTS

Welcome to Phoenix

Thank you to our members and partners who have traveled to Phoenix for the Winter 2025 NRG Oncology Meeting!

Our Meeting agenda has something to offer for every audience! The General Session gives a comprehensive overview of the ongoing activities in each of the areas of NRG Oncology. This session occurs on Friday, January 17th from 12:00-1:00pm. At the end of this session, The NRG Oncology Podcast will launch a special episode discussing our new Theranostics Subcommittee and the NRG Health Equity Fellowship Program. Another main session is the Scientific Session on Friday, January 17th from 3:00-4:00pm where you can hear about recent impactful results and publications that stemmed from NRG research. We will also be awarding our second NRG Gold Medal to an individual whose commitment to the missions of NRG has significantly advanced outcomes in the oncology community in this session.

This meeting will also be featuring the first ever combined GOG Foundation and NRG Oncology Symposium titled “Designing and Implementing Pragmatic Clinical Trials in Oncology” on Thursday, January 16th from 8:00am-12:00pm. If you have registered for this exclusive event, you will learn about the future of pragmatic clinical trial design across all disease sites.

All are invited to join us on Friday evening for the NRG Reception from 6:00-8:00pm. Attendees will have a chance to mingle among friends and network with new and familiar faces! We will also be serving refreshments to all guests.

If you are new to our NRG Meeting, please do not be afraid to speak up! We encourage all our members to actively participate in the different meeting sessions, which are designed to foster discussion. Your contributions during the NRG Meetings will provide the momentum to fuel the many great initiatives that NRG seeks to accomplish throughout the year.

Please browse the full meeting agenda in our Program Book to explore all the potential sessions you can participate in.

We hope you have a successful and exciting NRG Meeting experience.

Quynh-Thu Le, MD
NRG Oncology Group Chair

Robert Mannel, MD
NRG Oncology Group Chair

Norman Wolmark, MD
NRG Oncology Group Chair

NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG Oncology
Mission Statement

NRG Oncology seeks to improve the lives of cancer patients by conducting practice-changing multi-institutional clinical and translational research with emphases on gender-specific malignancies including gynecologic, breast, and prostate cancers and on localized or locally advanced cancers of all types.

For the Educational Objectives, we list the following:

- Inform the participants of the current state of clinical and basic oncologic research, particularly, but not exclusively as it relates to clinical trials.
- Provide participants with peer review critiques of progress (or lack of it) with the objective of self-improvement.
- Provide an opportunity to learn research administration and financial management in a cooperative group setting.
- Provide a forum for experts from diverse fields to improve research practices and patient management.

CONTINUING EDUCATION

CME Credit and PSC Contact Hours (Formerly CEUs)

ACCREDITATION

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the Joint Providership of The GOG Foundation, Inc. and NRG Oncology.

The GOG Foundation, Inc. is accredited by the ACCME to provide Continuing Education for physicians.

AMA PRA CATEGORY 1 CREDITS™

The GOG Foundation, Inc. designates this live activity for a maximum of **25.25 AMA PRA Category 1 Credits™**.

Physicians should claim only the credit commensurate with the extent of their participation in the activity.

HOW TO CLAIM CME CREDITS

1. **Scan QR Code** to Complete evaluation

Overall Meeting Evaluation: https://s.pointerpro.com/overalleval12025

Evaluation will not be active until the conclusion of the NRG Meeting (Jan 18th)

2. **Select Sessions** and **Enter Credits** being claimed

3. **Click Submit** and your CME certificate will automatically be emailed to you.

SYMPOSIUM

Symposium Evaluation links will be emailed to all registered attendees.

EVALUATIONS MUST BE SUBMITTED BY: FEBRUARY 3, 2025

DISCLOSURE DECLARATION

In compliance with ACCME regulations, The GOG Foundation, Inc., as the accredited provider of this activity, must ensure that anyone in a position to control the content of the educational activity has disclosed all relevant financial relationships with any commercial interest. All reported conflicts are managed by a designated official to ensure a bias-free presentation. Please see the complete disclosure list included with this program.

CONTACT HOURS (FORMERLY CEUS)

PSC Evaluation Links will be emailed to all registered attendees.

QUESTIONS

CMEs: If you have issues accessing your certificate or questions about CME please contact: cmeinfo@gog.org

PSC Contact Hours: For questions about Contact Hours (formerly CEUs) please contact: meeting-reg@NRGOncology.org

For questions or comments about this CME activity, please contact:
Michelle N. Small, MHA, Dir of Education Programs/CME Compliance at smallm@nrgoncology.org

GOG FOUNDATION®
Transforming the standard of care

CME Credit Listing

The following sessions/workshops have been approved to receive CME credits for the meeting January 13 - 18, 2025.
Maximum credits up to ***25.25*** *AMA PRA Category 1 Credits™*

Monday, January 13, 2025		Approved Credits	Credits Claimed
9:00 am – 11:00 am	Medical Oncology Committee	2.00	
11:00 am – 12:00 pm	Communications & Digital Engagement Workshop	1.00	
1:00 pm – 2:30 pm	Developmental Therapeutics-Radiation Therapy Subcommittee (DTRT)	1.50	

Tuesday, January 14, 2025		Approved Credits	Credits Claimed
9:00 am – 10:30 am	Pharmacy Subcommittee	1.50	
1:00 pm – 2:00 pm	Immunotherapy Subcommittee	1.00	

Thursday, January 16, 2025		Approved Credits	Credits Claimed
8:00 am – 9:15 am	NCORP Bootcamp	1.25	
11:00 am – 12:00 pm	Canadian Members Subcommittee	1.00	
12:00 pm – 1:30 pm	Cancer Care Delivery Research Committee (CCDR)	1.50	
12:30 pm – 2:30 pm	Developmental Therapeutics Committee	2.00	
1:00 pm – 3:00 pm	Pathology Committee	2.00	
1:45 pm – 3:15 pm	Cancer Prevention and Control Committee (CPC)	1.50	
3:00 pm – 5:00 pm	Translational Science Committee	2.00	
3:30 pm – 5:00 pm	Patient Centered Outcomes Research (PCOR)	1.50	

Friday, January 17, 2025		Approved Credits	Credits Claimed
8:00 am – 10:00 am	Cervix/Vulvar Cancer Subcommittee	2.00	
10:00 am – 11:30 am	NCORP Townhall	1.50	
10:00 am – 12:00 pm	Uterine Corpus Cancer Subcommittee	2.00	
1:00 pm – 3:00 pm	Ovarian Cancer Subcommittee	2.00	
3:00 pm – 4:30 pm	Scientific Session	1.50	
4:30 pm – 6:00 pm	Translational Science GYN Cancer Working Group	1.50	

Saturday, January 18, 2025		Approved Credits	Credits Claimed
7:30 am – 9:00 am	Genitourinary Cancer General Committee	1.50	
7:45 am – 9:30 am	Gynecologic Cancer Committee	1.75	

The NRG Oncology *Demographic Data* INITIATIVE

To better understand our membership, NRG Oncology is creating a membership database that will contain demographic information for our members and staff. We are asking all members to participate, even if your preferred level of engagement is opting out entirely. For those that elect to opt in, answering the brief set of demographic questions will take less than three minutes to complete. Most questions include a "prefer not to answer" option. The self-reported information you provide will be stored securely and accessed only by authorized NRG personnel.

Scan the QR code below to access the form.

NRGOncology.org/Demographic-Data-Initiative

NRG2025
at your finger tips

Twitter / X
@NRGOnc

Facebook
@NRG Oncology

Instagram
@NRGOnc

LinkedIn
@NRG Oncology

YouTube
@NRGOnc

Use the hashtag **#NRG2025** to join the conversation.

CONNECT TO WIFI

Network Login: nrgmeeting
Passcode: n1r2g345

CHECK OUT OUR MEETING WEBPAGES

The NRG2025 main agenda, session flyers, attendee information, and more are posted on our NRG2025 webpages located at:
www.nrgoncology.org/NRGWinter2025

Continue to check these pages after NRG2025 ends as we will update this section with any available presentation slides and recordings.

Meeting App

1. Go to the Apple Store or Google Store
2. Download the CVENT Events App
3. Select CVENT EVENTS
4. Search for Event = NRG
5. Select: "NRG Oncology Winter 2025 Meeting"
6. Event ID = NRG ONCW25
   (Please note there is a space after NRG)

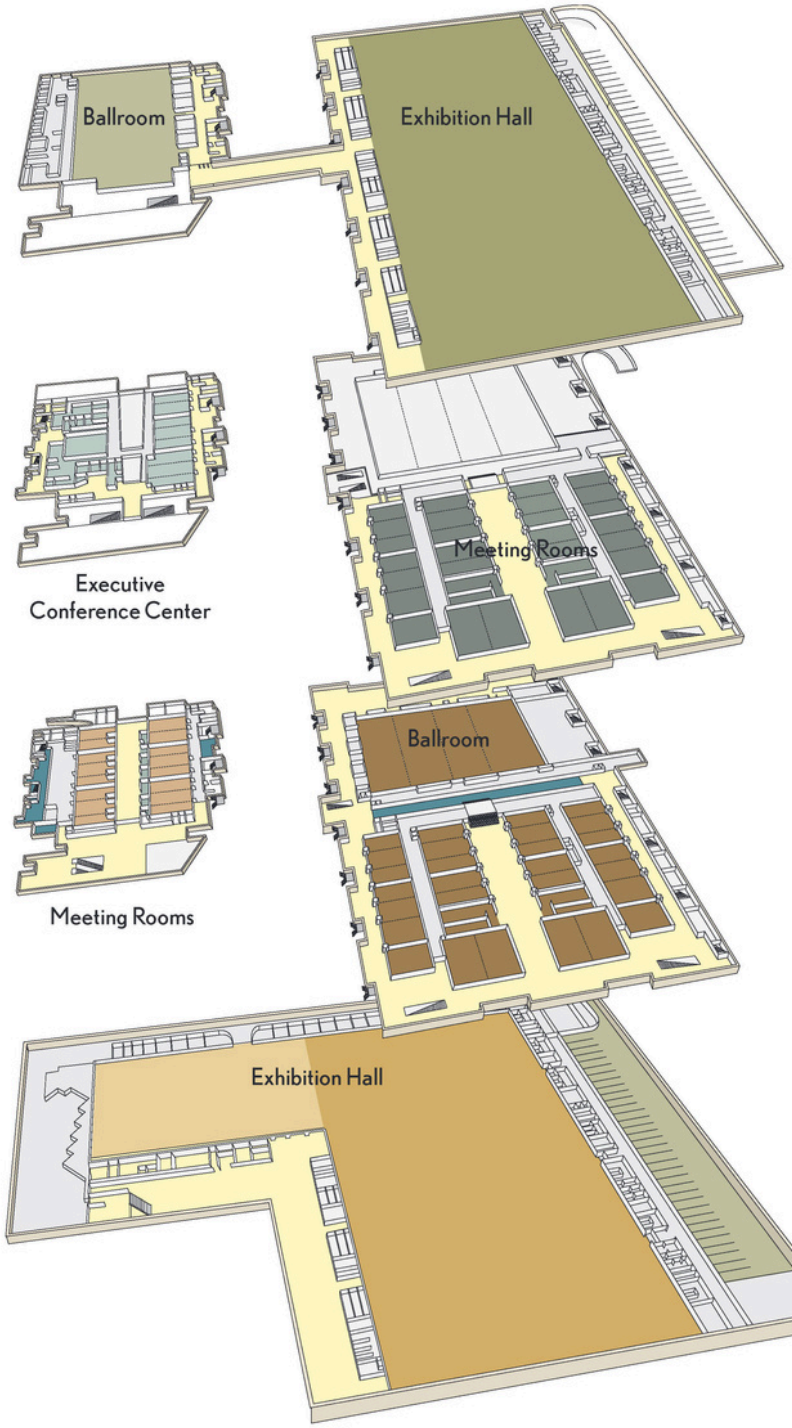
Once you are in the NRG Oncology Winter Meeting, enter your first name, last name, and the email that you used to register for the event.

You'll receive a 6-digit verification code to your email. Enter the code on the screen. Tap the arrow.

Opt in to receive push notifications so you don't miss any important information!

Venue Map

WEST BUILDING NORTH BUILDING



300 LEVEL

WEST BUILDING	NORTH BUILDING
45,200 SF West Ballroom Riser seating for 1,200	190,000 SF Exhibition Hall

200 LEVEL

WEST BUILDING	NORTH BUILDING
21,000 SF Conference Center IACC Certified 192-Seat Lecture Hall	43,000 SF Meeting Rooms

100 LEVEL

WEST BUILDING	NORTH BUILDING
27,200 SF Meeting Rooms	45,600 SF Ballroom 43,000 SF Meeting Rooms

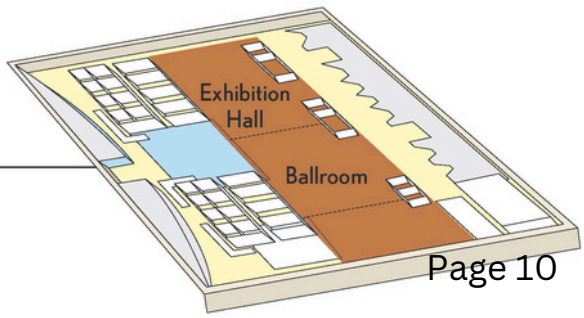
LOWER LEVEL

WEST BUILDING	NORTH BUILDING
312,500 Total Combined SF Exhibition Hall	

100 LEVEL
SOUTH BUILDING

28,000 SF Ballroom
82,000 SF Exhibition Hall
33,000 SF Meeting Space

Expands to 143,000 SF Expo Hall



NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Phoenix Convention Center
Phoenix, AZ
January 16 - 18, 2025 (All Sessions Mountain Standard Time)

Monday, January 6, 2025		
1:00 pm – 2:30 pm	Translational Science Brain Tumor Working Group	Virtual Only
Tuesday, January 7, 2025		
1:00 pm – 2:00 pm	Breast Cancer Rare Tumor Working Group	Virtual Only
1:00 pm – 2:30 pm	Translational Science Genitourinary Cancer Working Group	Virtual Only
Wednesday, January 8, 2025		
11:30 am – 1:00 pm	Head & Neck Recurrent/Metastatic Working Group	Virtual Only
1:00 pm – 2:00 pm	Head & Neck Health Equity/Diversity Working Group	Virtual Only
1:30 pm – 4:00 pm	NRG-HN014 Kick-Off Study Training Webinar	Virtual Only
Thursday, January 9, 2025		
12:00 pm – 2:00 pm	Hematologic Malignancies Working Group	Virtual Only
Friday, January 10, 2025		
8:00 am – 10:00 am	Translational Science Lung Cancer Working Group	Virtual Only
10:00 am – 11:00 am	Local Regional Breast Cancer Working Group	Virtual Only
Monday, January 13, 2025		
9:00 am – 10:00 am	Head & Neck Previously Untreated Locoregionally Advanced Working Group	Virtual Only
9:00 am – 11:00 am	Medical Oncology Committee	Virtual Only
10:00 am – 11:00 am	VA/MTF Subcommittee	Virtual Only
11:00 am – 12:00 pm	Communications & Digital Engagement Workshop (formerly Social Media)	Virtual Only
11:00 am – 12:00 pm	Translational Science Breast Cancer Working Group	Virtual Only
11:30 am – 1:00 pm	Imaging Subcommittee Meeting	Virtual Only
1:00 pm – 1:30 pm	Joint Imaging & Medical Physics Seminar	Virtual Only
1:30 pm – 3:00 pm	Medical Physics Subcommittee Meeting	Virtual Only
1:00 pm – 2:30 pm	Developmental Therapeutics-Radiation Therapy Subcommittee	Virtual Only
Tuesday, January 14, 2025		
7:30 am – 8:30 am	Head & Neck Rare Tumor Working Group	Virtual Only
9:00 am – 10:30 am	Pharmacy Subcommittee	Virtual Only
10:00 am – 11:00 am	Translational Science Head & Neck Cancer Working Group	Virtual Only
11:00 am – 12:00 pm	QA Subcommittee *(Closed)*	Virtual Only
11:00 am – 12:30 pm	Adaptive Radiation Therapy Working Group	Virtual Only
1:00 pm – 2:00 pm	Immunotherapy Subcommittee	Virtual Only

Revised 1/7/2025

All sessions will be in-person unless noted.

NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Phoenix Convention Center
Phoenix, AZ
January 16 - 18, 2025 (All Sessions Mountain Standard Time)

Thursday, January 16, 2025		
6:30 am – 7:30 am	Protocol Support Committee Nurse/CRP Breakfast	West 301D / 3rd Level
6:30 am – 8:00 am	Symposium Breakfast	West 301AB / 3rd Level
7:00 am – 6:00 pm	Exhibits	West 301D Lobby / 3rd Level
7:00 am – 6:00 pm	Registration/Information Desk	West 301A Lobby / 3rd Level
2:00 pm – 4:00 pm	General Coffee Break	West 301D Lobby / 3rd Level
7:30 am – 12:05 pm	Protocol Support Committee Nurse/CRA Introduction to Clinical Trials: Principles of Clinical Trial Management (Webinar / In Person)	West 301D / 3rd Level
8:00 am – 10:00 am	NCORP Bootcamp	West 213AB / 2nd Level
8:00 am – 12:00 pm	Winter Symposium: *"Designing and Implementing Pragmatic Clinical Trials in Oncology"* (Webinar / In Person)	West 301AB / 3rd Level
10:00 am – 11:00 am	International Members Meeting (Virtual / In Person)	West 211AB / 2nd Level
10:15 am – 11:15 am	Health Disparities Committee Meeting	West 212ABC / 2nd Level
11:00 am – 12:00 pm	Diversity, Equity, and Inclusion Committee *(Closed)*	West 208A / 2nd Level
11:00 am – 12:00 pm	Canadian Members Meeting (Virtual / In Person)	West 211AB / 2nd Level
11:30 am – 12:00 pm	Health Disparities Breakout Session: Concept Development SIG	West 101A / 1st Level
11:30 am – 12:00 pm	Health Disparities Breakout Session: Older Adult Research SIG	West 106C / 1st Level
11:30 am – 12:00 pm	Health Disparities Breakout Session: Research Implementation SIG	West 101C / 1st Level
11:30 am – 12:00 pm	Health Disparities Breakout Session: Rural Research SIG	West 102C / 1st Level
12:00 pm – 1:30 pm	Cancer Care Delivery Research Committee	West 105BC / 1st Level
12:15 pm – 1:45 pm	Membership Committee Meeting *(Closed)*	West 208A / 2nd Level
12:30 pm – 2:30 pm	Developmental Therapeutics Committee	West 301C / 3rd Level
1:00 pm – 3:00 pm	Pathology Committee	West 106B / 1st Level
1:30 pm – 4:25 pm	Protocol Support Committee Nurse/CRP Introduction to Clinical Trials: Discussion Sessions (Virtual / In Person)	West 101A, West 101C, West 102C, West 106C / 1st Level
1:45 pm – 3:15 pm	Cancer Prevention and Control Committee	West 105BC / 1st Level
2:30 pm – 4:00 pm	Early Career and New Investigator Educational Session	West 301AB / 3rd Level
2:30 pm – 4:30 pm	Rare Tumor Subcommittee	West 301C / 3rd Level
3:00 pm – 4:00 pm	Theranostics Subcommittee	West 213AB / 2nd Level
3:00 pm – 5:00 pm	Ancillary Projects Committee *(Closed)*	West 101B / 1st Level
3:00 pm – 5:00 pm	Translational Science Committee	West 301D / 3rd Level
3:30 pm – 5:00 pm	Patient Centered Outcomes Research (PCOR) Committee	West 212ABC / 2nd Level
4:00 pm – 5:00 pm	Early Career and New Investigator Networking Session	West 301AB / 3rd Level

Revised 1/7/2025

All sessions will be in-person unless noted.

NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Phoenix Convention Center
Phoenix, AZ
January 16 - 18, 2025 (All Sessions Mountain Standard Time)

Thursday, January 16, 2025		
4:30 pm – 6:00 pm	Patient Advocates Committee Meeting *(Invitation Only)* Virtual / In Person	West 211AB / 2nd Level
5:00 pm – 6:30 pm	PSC Education & Training Subcommittee *(Closed)*	West 101B / 1st Level
5:00 pm – 6:30 pm	PSC Mentorship Subcommittee *(Closed)*	West 102A / 1st Level
5:00 pm – 6:30 pm	PSC Protocol Review Subcommittee *(Closed)*	West 102B / 1st Level
5:00 pm – 6:30 pm	PSC Quality Control & Communications Subcommittee *(Closed)*	West 208A / 2nd Level
5:15 pm – 6:30 pm	Committee Chairs Meeting *(Invitation Only)*	West 213AB / 2nd Level
5:30 pm – 6:30 pm	Radiation Oncology Gynecologic Working Group	West 105BC / 1st Level

NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Phoenix Convention Center
Phoenix, AZ
January 16 - 18, 2025 (All Sessions Mountain Standard Time)

Friday, January 17, 2025		
6:30 am – 8:30 am	Continental Breakfast	West 301D Lobby / 3rd Level
7:00 am – 5:00 pm	Exhibits	West 301D Lobby / 3rd Level
7:00 am – 5:30 pm	Registration/Information Desk	West 301A Lobby / 3rd Level
10:00 am – 12:00 pm	General Coffee Break	West 301D Lobby / 3rd Level
3:00 pm – 5:00 pm	General Coffee Break	West 301D Lobby / 3rd Level
6:00 am – 7:30 am	Endometrial Consortium, Route 66 SPORE & Protocol 210 Meeting *(Closed)*	West 102A / 1st Level
7:00 am – 8:00 am	Voting Members PI Breakfast *(Closed)*	North 229AB / 2nd Level
7:30 am – 10:00 am	Brain Tumor Core Committee *(Closed)*	North 222ABC / 2nd Level
7:30 am – 11:45 am	Protocol Support Committee Nurse/CRA- Continuing Education Session (Webinar / In Person)	West 301D / 3rd Level
8:00 am – 10:00 am	Cervix/Vulva Cancer Subcommittee	West 301C / 3rd Level
8:00 am – 10:00 am	Head & Neck Surgical Working Group	West 101A / 1st Level
8:00 am – 10:00 am	Radiation Oncology Committee	North 224AB / 2nd Level
9:00 am – 12:00 pm	Breast Cancer Core Committee *(Closed)*	West 301AB / 3rd Level
10:00 am – 11:30 am	NCORP Townhall	West 212ABC / 2nd Level
10:00 am – 12:00 pm	Head & Neck Cancer Core Committee *(Closed)*	West 211AB / 2nd Level
10:00 am – 12:00 pm	Sarcoma Working Group	West 101A / 1st Level
10:00 am – 12:00 pm	Uterine Corpus Cancer Subcommittee	West 301C / 3rd Level
10:15 am – 11:45 am	Neurosurgical Working Group	West 213AB / 2nd Level
10:15 am – 11:45 am	Particle Working Group	North 224AB / 2nd Level
12:00 pm – 1:00 pm	General Session	West 301D / 3rd Level
1:00 pm – 3:00 pm	Genitourinary Cancer Core Committee *(Closed)*	West 213AB / 2nd Level
1:00 pm – 3:00 pm	Lung Cancer Core Committee *(Closed)*	West 105A / 1st Level
1:00 pm – 3:00 pm	Ovarian Cancer Subcommittee	West 301C / 3rd Level
1:15 pm – 2:45 pm	Brain Tumor General Committee	North 222ABC / 2nd Level
2:00 pm – 3:00 pm	Health Disparities Committee SIG Leadership Meeting *(Closed)*	West 208A / 2nd Level
3:00 pm – 4:30 pm	Scientific Session	West 301D / 3rd Level
4:30 pm – 6:00 pm	Head & Neck Cancer General Committee	West 301AB / 3rd Level
4:30 pm – 6:00 pm	PSC CTN/CRA Joint Subcommittee Meeting *(Closed)*	West 102B / 1st Level
4:30 pm – 6:00 pm	Translational Science GYN Cancer Working Group	Virtual Only
4:30 pm – 6:15 pm	Lung Cancer General Committee	West 212ABC / 2nd Level
5:00 pm – 7:00 pm	Korean Gynecologic Oncology Group	West 105A / 1st Level
6:00 pm – 8:00 pm	NRG Oncology Reception	North 230, North 231ABC, North 232ABC / 2nd Level

Revised 1/7/2025

All sessions will be in-person unless noted.

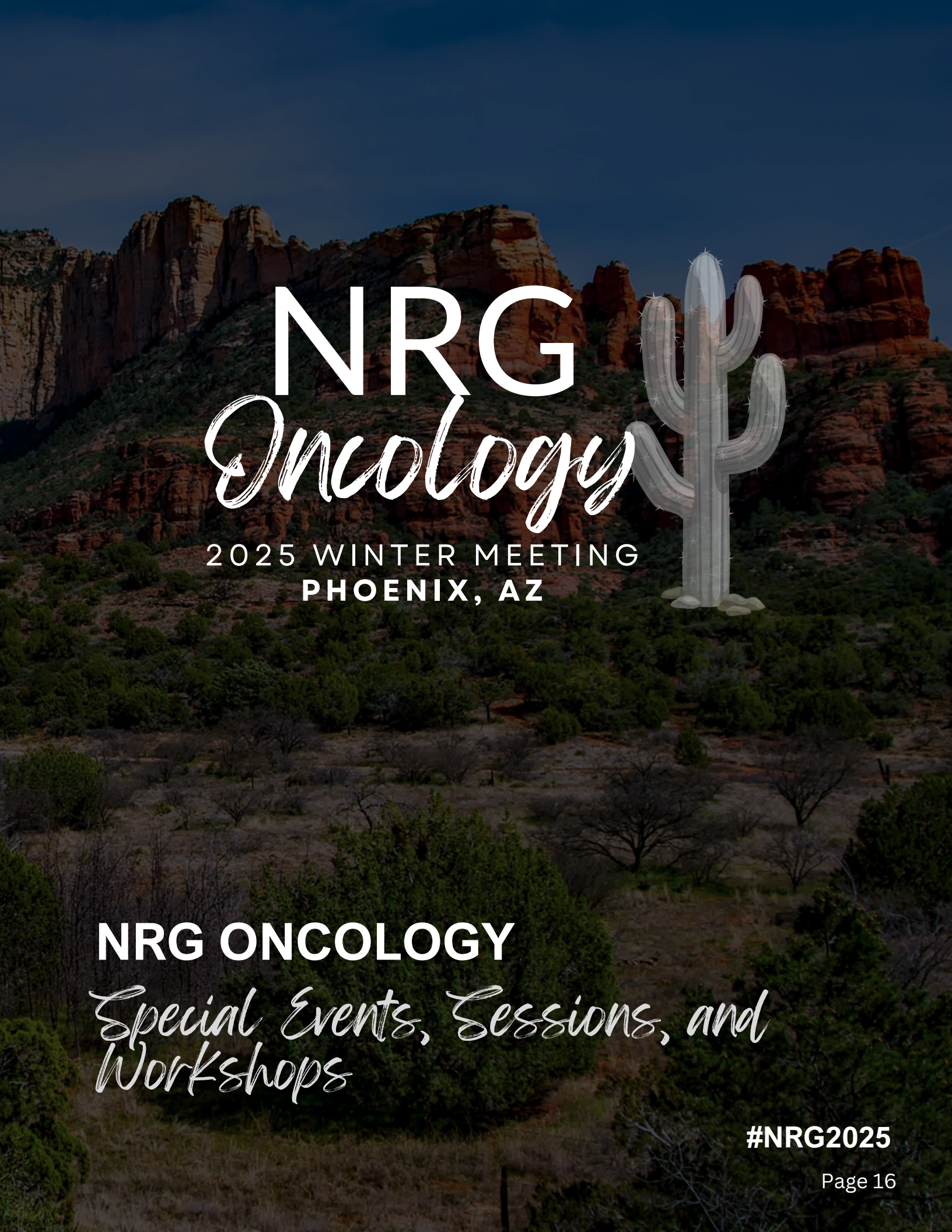
NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG ONCOLOGY SEMIANNUAL MEETING
FINAL AGENDA

Phoenix Convention Center
Phoenix, AZ
January 16 - 18, 2025 (All Sessions Mountain Standard Time)

Saturday, January 18, 2025		
6:30 am – 10:00 am	Continental Breakfast	West 301D Lobby / 3rd Level
7:00 am – 12:30 pm	Exhibits	West 301D Lobby / 3rd Level
7:00 am – 12:30 pm	Registration/Information Desk	West 301A Lobby / 3rd Level
6:30 am – 8:00 am	Surgical Oncology Committee	West 211AB / 2nd Level
7:00 am – 8:00 am	NRG-BR009 Workshop	West 301AB / 3rd Level
7:30 am – 9:00 am	Gastrointestinal Colorectal Cancer Core Committee *(Closed)*	West 213AB / 2nd Level
7:30 am – 9:00 am	Genitourinary Cancer General Committee	West 212ABC / 2nd Level
7:30 am – 9:00 am	Protocol Operations Management Committee *(Closed)*	West 101B / 1st Level
7:45 am – 9:30 am	Gynecologic Cancer Committee	West 301C / 3rd Level
8:00 am – 9:00 am	NRG-BR008 Workshop	West 301AB / 3rd Level
8:00 am – 10:30 am	PSC Core Executive Committee *(Closed)*	West 208A / 2nd Level
9:00 am – 12:00 pm	Breast Cancer General Committee	West 301AB / 3rd Level
9:15 am – 10:45 am	Gastrointestinal Non-Colorectal Cancer Core Committee *(Closed)*	West 213AB / 2nd Level
11:00 am – 12:30 pm	Gastrointestinal Cancer General Committee	West 212ABC / 2nd Level



NRG ONCOLOGY

Special Events, Sessions, and Workshops

#NRG2025

THE NRG ONCOLOGY PODCAST

Moving the needle in cancer care

with Co-hosts

Stephen Chun, MD

&

Lauren Henke, MD

2025 ACRO
Media Award Recipient

LISTEN ON:

SPOTIFY

APPLE PODCASTS

YOUTUBE

AMAZON MUSIC

THE NRG ONCOLOGY PODCAST

Moving the needle in cancer care

NRG Oncology 2025 WINTER MEETING PHOENIX, AZ

Available after the #NRG2025 General Session at Phoenix.

TOPICS:

THE NEW NRG THERANOSTICS SUBCOMMITTEE

Interview with Dr. Jeff Michalski, Subcommittee Chair

THE NRG HEALTH EQUITY FELLOWSHIP

Interview with Dr. Joan Walker

SPECIAL EPISODE

LISTEN ON:

SPOTIFY

APPLE PODCASTS

YOUTUBE

AMAZON MUSIC

Protocol Support Committee

Introduction to Clinical Trials:
Principles of NRG Oncology Clinical Trial Management for Nurse/CRAs

Thursday, January 16, 2025
7:30 am - 4:30 pm MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ

Program Facilitators

Cynthia Licavoli, RN, BSN, MHA
Marissa Weiss, MBA
Jacqueline Ludwig, RN, BSN, CCRP

Presentations in-person & virtual

Morning Presentations

Sharon Hartson Stine, MS, BA
NRG Oncology Overview

Karan Boparai, BS, (R)(M)
NRG Oncology Membership

Judy Langer, BS
Regulatory Affairs

Sara McCartney, MS, RN
Expedited Adverse Event Reporting

Erica Gray, PharmD, BCPS
Investigational Drug Management

Joseph Mroziak
Medidata Rave

Mary Jo Antonelli, MBA, MHA
Quality Assurance Audits

Lisa Beverson, BA, CCRP
Pathology/Biospecimen Collections

Shannon Puhalla, MD
RECIST Criteria

Nancy Fusco, RN, BSN, CCRP
Mentorship Program

Kandie Dempsey, DBA, MS, RN, OCN
Patient Reported Outcome Compliance

Afternoon Discussion Sessions

Patient Screening & Enrollment
Lead Facilitator: **Cindy Licovali, RN, BSN, MHA**
Erin McCaig, RN, BSN
Tiffany Elsea, BA, CCRP

Treatment Modalities in Clinical Trial Management
Lead Facilitator: **Terry Thomas, MS, CCRC**
Pamela Mason, RN, BSN, CCRP
Allison Ivey, RN, MS, MBA, OCN, CCRP

Data Management
Lead Facilitator: **Alex Kudryashev, MS, CCRP**
Mark Fisher, BS, CCRP
Rachel Lacy, BA, MPH

Adverse Event Reporting
Lead Facilitator: **Cortney Montgomery, BSN, RN, CCRP, CBCN**
Stacy Lewis, RN, BSN, OCN
Brittany Lansford, CCRC

This nursing continuing professional development activity was approved by the Virginia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Protocol Support Committee
Introduction to Clinical Trials: Principles of NRG Oncology Clinical Trial Management for Nurse/CRAs

Date:	**Thursday, January 16, 2025**
Start and End Time:	**7:30 am MT – 4:30 pm MT (presentations in-person & virtual)**
PSC Chair:	**Terry Thomas MS, CCRC**
PSC Vice-Chairs:	**Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MHA**
Program Facilitators:	**Cynthia Licavoli RN, BSN, MHA, Marissa Weiss, MBA & Jacqueline Ludwig, RN, BSN, CCRP**

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss NRG Oncology membership requirements.
2. Identify and describe relevant regulations for federally funded clinical research involving human subjects.
3. Describe the processes to be followed by clinical research sites in adhering to IRB requirements.
4. Describe the key components of adverse event assessment for expedited reporting including seriousness criteria, term selection, grading and attribution.
5. Describe the standard drug accountability procedures for NCTN trials.
6. Identify and discuss resources regarding investigational drug management.
7. Discuss and navigate the Rave data management system.
8. Utilize basic commands to key data into the RAVE system.
9. Discuss the nature of and preparation for NCI-mandated Quality Assurance Audits.
10. Discuss the basics of pathology and translational research specimen requirements and submissions.
11. Describe the basic methodology of RECIST 1.1 and other response criteria used in NRG Oncology trials.
12. Discuss RECIST 1.1 criteria as well as other response criteria used and identify methods of source documentation.
13. Identify and discuss key components of Patient Reported Outcomes (PRO) compliance
14. Discuss NRG Oncology Mentorship Program.
15. Discuss patient screening and enrollment process and identify best practices.
16. Identify methods for screening patients for clinical trials.
17. Identify the informed consent process according to federal regulations and local practices.
18. Discuss protocol requirements for administration of chemotherapy, immunotherapy, radiation therapy and surgery.
19. Describe useful tools and methods to ensure timely and accurate data management in the clinical trial setting.
20. Identify proper forms of source documentation.
21. Describe procedures for completion and submission of case report forms.

AGENDA

Time	**Presentation**	**Speakers**
7:30 am- 7:40 am	Welcome	Cindy Licavoli, RN, BSN, MHA
7:40 am- 7:50 am	NRG Oncology Overview	Sharon Hartson Stine, MS, BA
7:50 am- 8:10 am	NRG Oncology Membership	Karan Boparai, BS, (R)(M)
8:10 am- 8:35 am	Regulatory Affairs	Judy Langer, BS
8:35 am-9:05 am	Expedited Adverse Event Reporting	Sara McCartney, MS, RN
9:05 am-9:35 am	Investigational Drug Management	Erica Gray, PharmD, BCPS
9:35 am-9:50 am	***Break***	

9:50 am- 10:15 am	Medidata Rave	Joseph Mroziak
10:15 am-10:45 am	Quality Assurance Audits	Mary Jo Antonelli, MBA, MHA
10:45 am-11:05 am	Pathology/Biospecimen Collections	Lisa Beaverson, BA, CCRP
11:05 am-11:40 am	RECIST Criteria	Shannon Puhalla, MD
11:40 am – 11:50 am	Mentorship Program	Nancy Fusco, RN, BSN, CCRP
11:50 am – 12:00 pm	Patient Reported Outcome Compliance	Kandie Dempsey, DBA, MS, RN, OCN
12:00 pm- 12:05 pm	Morning Closing Remarks	Cindy Licavoli, RN, BSN, MHA
12:05 pm – 1:30 pm	***Lunch Break on your own***	

Afternoon Discussion Sessions (each session will be presented in-person and virtually during this time frame):

1:30 pm – 4:30 pm

Patient Screening & Enrollment	*Lead Facilitator*- Cindy Licavoli, RN, BSN, MHA Erin McCaig, RN, BSN Tiffany Elsea, BA, CCRP
Treatment Modalities in Clinical Trial Management	*Lead Facilitator*-Terry Thomas, MS, CCRC Pamela Mason, RN, BSN, CCRP Alison Ivey, RN, MS, MBA, OCN, CCRP
Data Management	*Lead Facilitator*-Alex Kudryashev, MS, CCRP Mark Fischer, BS, CCRP Rachel Lacy, BA, MPH
Adverse Event Reporting	*Lead Facilitator*- Cortney Montgomery BSN, RN, CCRP, CBCN Stacey Lewis, RN, BSN, OCN Brittany Lansford, CCRC
4:25 pm- 4:30 pm	Evaluation

This nursing continuing professional development activity was approved by the Virginia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

WINTER 2025 SYMPOSIUM

Designing and Implementing Pragmatic Clinical Trials in Oncology

Thursday, January 16, 2025 - 8 - 12 pm MT- Phoenix, Arizona

Target Audience: *Members and non-members including our broad audience of physicians, research staff, new investigators, clinical research associates, basic researchers, medical physics, clinical trial nurses, patient advocates and other health care professionals interested in the treatment of cancer.*

Program Description

A new type of trial design is coming to NRG. The upcoming Winter 2025 Educational Symposium will highlight the value of pragmatic clinical trials across oncology and include examples of trials in lung, breast, and gynecologic cancers. This symposium is for everyone involved in oncology clinical trials and will help define the role of pragmatic trials and the effect of treatment in routine clinical practice. The speakers will focus their presentations on the design and conduct of pragmatic clinical trials, review the regulatory landscape, and describe the components of a successful pragmatic clinical trial, including how to improve health equity in clinical trials. The session will include didactic lectures from content experts as well as case studies from current NRG trials. The symposium will also incorporate question and answer sessions for audience participation. The speakers represent a multidisciplinary team, including the patient perspective.

Learning Objectives

- Define and clarify the key components of a pragmatic clinical trial
- Explain the role of pragmatic clinical trials in conducting effective clinical research in real-world settings
- Design and implement effective pragmatic clinical trials to enroll more diverse patient populations

Session 1 Introduction to Pragmatic Clinical Trials	Welcome and Introduction - Program Chairs: Ying Liu, MD, MPH & Carol Aghajanian, MD What is a Pragmatic Clinical Trial? - Kathleen Moore, MD Why are Pragmatic Clinical Trials Important? NIH Perspective - Meg Mooney, MD, MS Lung Pragmatic Trial - Karen L. Reckamp, MD Q/A with Speakers
Session 2 Designing a Pragmatic Clinical Trial	Eligibility Criteria - Practicality and Inclusivity - Carol Aghajanian, MD Incorporating Pragmatic Elements into Oncology Trial Designs - Mei-Yin Polley, PhD Leveraging Technology and Real-World Data to Streamline Trials - Neal Meropol, MD Optimizing the EHR for Pragmatic Clinical Trials - James C. Yao, MD How to Reach Diverse Populations & Improve Health Equity - Bhavana Pothuri, MD, MS Q/A with Speakers
Session 3 Implementing a Pragmatic Clinical Trial	NRG-GY036: Case Study for a Pragmatic Trial- Ying Liu, MD, MPH NRG-BN014: Case Study for a Pragmatic Trial - Jonathan Yang, MD, PhD Logistics of Data Management & AE Reporting - Elaina Harper, BS & Sara McCartney, MS, RN Patient Perspective on Pragmatic Clinical Trials - Dorothy Erlanger Q/A with Speakers Closing Remarks

CME Information:
Accreditation Statement: The GOG Foundation, Inc. is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide Continuing Medical Education for physicians.

AMA PRA Category 1 Credits™ The GOG Foundation, Inc. designates this live internet activity for a maximum of 4 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Sponsored by NRG Oncology and The GOG Foundation, Inc.

Winter 2025 Symposium Agenda

"Designing and Implementing Pragmatic Clinical Trials in Oncology"

Jan 16, 2025 – 8 am to 12 pm (MT) - NRG Oncology Winter 2025 Meeting – Phoenix, AZ

Program Chair: Ying Liu, MD, MPH, Co-Chair: Carol Aghajanian, MD

PROGRAM DESCRIPTION:

A new type of trial design is coming to NRG. The upcoming Winter 2025 Educational Symposium will highlight the value of pragmatic clinical trials across oncology and include examples of trials in lung, breast, and gynecologic cancers. This symposium is for everyone involved in oncology clinical trials and will help define the role of pragmatic trials and the effect of treatment in routine clinical practice. The speakers will focus their presentations on the design and conduct of pragmatic clinical trials, review the regulatory landscape, and describe the components of a successful pragmatic clinical trial, including how to improve health equity in clinical trials. The session will include didactic lectures from content experts as well as case studies from current NRG trials. The symposium will also incorporate question and answer sessions for audience participation. The speakers represent a multidisciplinary team, including the patient perspective.

TARGET AUDIENCE: This educational activity is directed towards members and non-members including our broad audience of physicians, research staff, new investigators, clinical research associates, basic researchers, medical physics, clinical trial nurses, patient advocates and other health care professionals interested in the treatment of cancer.

LEARNING OBJECTIVES: *Following this activity, participants will be better able:*

1. To define and clarify the key components of a pragmatic clinical trial
2. To explain the role of pragmatic clinical trials in conducting effective clinical research in real-world settings
3. To design and implement effective pragmatic clinical trials to enroll more diverse patient populations

Presentation Agenda		
Time	**Topic/Title**	**Speaker/Moderator**
8:00 am	**Welcome/Opening Remarks**	
8:05 am	**Session 1: Introduction to Pragmatic Clinical Trials**	**Moderator: Carol Aghajanian**
8:05 – 8:15	What is a Pragmatic Clinical Trial?	Kathleen Moore, MD
8:15 – 8:30	Why are Pragmatic Clinical Trials Important? NIH Perspective	Meg Mooney, MD, MS
8:30 – 8:45	Lung Pragmatica Trial	Karen L. Reckamp, MD
8:45 – 9:00	**Q/A**	
9:00– 9:10	**Break**	
9:10 am	**Session 2: Designing a Pragmatic Clinical Trial**	**Moderator: Ying Liu**
9:10 – 9:25	Eligibility Criteria – Practicality and Inclusivity	Carol Aghajanian, MD
9:25- 9:40	Incorporating Pragmatic Elements Into Oncology Trial Designs	Mei-Yin Polley, PhD
9:40 – 9:55	Leveraging Technology and Real-World Data to Streamline Trials	Neal Meropol, MD
9:55-10:10	Optimizing the EHR for Pragmatic Clinical Trials	James C. Yao, MD
10:10 – 10:25	How to Reach Diverse Populations and Improve Health Equity	Bhavana Pothuri, MD, MS
10:25 – 10:40	**Q/A**	
10:40 – 10:50	**Break**	
10:50 am	**Session 3: Implementing a Pragmatic Clinical Trial**	**Moderator: Carol Aghajanian**
10:50 – 11:05	NRG-GY036: Case Study for a Pragmatic Clinical Trial	Ying Liu, MD, MPH
11:05– 11:20	NRG-BN014: Case Study for a Pragmatic Clinical Trial	Jonathan Yang, MD, PhD
11:20 - 11:30	Logistics of Data Management and AE Reporting	Elaina Harper, BS Sara McCartney, MS, RN
11:30– 11:40	Patient Perspective on Pragmatic Clinical Trials	Dorothy Erlanger
11:40 – 11:55	**Q/A**	
11:55- 12:00 pm	Closing Remarks	Ying Liu, MD, MPH

NCORP Bootcamp

Thursday, January 16, 2025
8:00-10:00 am MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ

Agenda

Deborah Bruner, PhD, RN
NRG NCORP PI

Welcome, introductions, & goals for the workshop

Lisa Kachnic, MD
NRG NCORP Co-PI

Overview of NRG Oncology NCORP

Benjamin Movsas, MD
Patient Centered Outcomes Research Committee Chair

Julie Bauman, MD
Cancer Prevention Committee Chair

Mary Cooley, PhD, RN, FAAN
Cancer Care Delivery Committee Chair

Jennifer Wenzel, PhD, MS, RN
Health Disparities Research Committee Chair

Introduction to NRG NCORP PCOR, CPC, CCDR, & HDC

Aims of each committee and types of trials run through each.

Stephanie Pugh, PhD
Deputy Director NCORP Statistics

Statistical Considerations

Tracy Crane, PhD
Cancer Control Committee Vice Chair

R01 Overview

All

Discussion / Q&A

Session Title	NCORP Bootcamp		
Date	January 16, 2025	**Chair(s)**	Deborah Bruner, PhD, RN; Lisa Kachnic, MD
Time	8:00 – 9:15amMT	**Vice Chair(s)**	

Learning Objectives

Following this activity, participants will be better able to:

1. Identify priority areas for NRG NCORP research in cancer prevention and control, cancer care delivery research and health disparities research.
2. Learn about statistical design considerations for an NCORP concept.
3. Apply procedures required to design, submit and conduct an NCORP research protocol for support by NRG.

Meeting Agenda

Time	Topic	Presenter
8:00 – 8:10am	Welcome, introductions, goals for the workshop	Deb Bruner, PhD, NCORP PI
8:10 – 8:25am	Overview of NRG Oncology NCORP	Lisa Kachnic, MD, NCORP Co-PI
8:25 – 8:45am	Introduction to NRG NCORP committees: Patient Centered Outcomes Research (PCOR), Cancer Prevention and Control (CPC), Cancer Care Delivery Research (CCDR), and Health Disparities (HD) Aims of each committee and *types of trials run through each.*	Ben Movsas, MD, Patient Centered Outcomes Research Julie Bauman, MD, Cancer Prevention Committee Chair Mary Cooley, PhD, Cancer Care Delivery Research Committee Chair Jennifer Wenzel, PhD, Health Disparities Committee Chair
8:45 – 8:55am	Statistical Considerations	Stephanie Pugh, PhD, Deputy Director NCORP Statistics
8:55 – 9:05am	R01 Overview	Tracy Crane, PhD, Cancer Control Committee Vice-Chair
9:05 – 9:15am	Discussion / Q&A	

Pathology Committee

Thursday, January 16, 2025
1-3pm MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ
#NRG2025

Session Co-Chairs

Jeffry Simko, MD, PhD
Pathology Chair

Tan Ince, MD, PhD
Pathology Vice Chair

Tanner Freeman, MD, PhD
Pathology Vice Chair

Presenters

Erin Stewart, PhD
Artera

Precision Medicine in Pixels: Prognostic & Predictive AI-derived Digital Pathology Biomarkers

Fiona McAlister, PhD
Southern Oklahoma Technology Center

From Bench to Bedside - A Patient's Journey Translating Science Into Survival

Jeffry Simko, MD, PhD
UCSF

U10 and U24 Grant Update Planning

All Participants

Trial and Pathology Project Updates

Other Business

Session Title	Pathology Committee		
Date	January 16, 2024	**Chair(s)**	Jeffry Simko, MD, PhD; Tan Ince, MD, PhD; Tanner Freeman, MD, PhD
Time	1:00PM - 3:00 pm MT	**Vice Chair(s)**	

Learning Objectives

Following this activity, participants will be better able to:

1. Better understand the significance and role of Pathology within Cancer Clinical Trials in general, and NRG Trials specifically.
2. Learn how artificial intelligence image analysis (AIIA) will impact pathology and how it can be leveraged to improve pathology practice and patient care.
3. Improve understanding of cancer patient perspectives in relation to their care and experiences, so as to improve oncologic outcomes and to more effectively direct research and care improvement.

Meeting Agenda

Time	Topic	Presenter
1:00 – 1:05 pm	Welcome and Introductions	Jeffry Simko, MD, PhD (University of California, San Francisco)
1:05 – 1:30 pm	Precision Medicine in Pixels: Prognostic & Predictive AI-derived Digital Pathology Biomarkers	Erin Stewart, PhD (Artera)
1:30 – 2:00 pm	From Bench to Bedside - A Patient's Journey Translating Science Into Survival	Fiona McAlister, PhD (Southern Oklahoma Technology Center)
2:00– 2:10 pm	U10 and U24 Grant Update Planning	Jeffry Simko, MD, PhD
2:10 – 2: 25 pm	Trial and Pathology Project Updates	All Participants
2:25 – 2:40 pm	Other business	All Participants
2:40 – 2: 45 pm	Closing remarks	Jeffry Simko, MD, PhD

Additional Notes:

Translational Science Committee

Thursday, January 16, 2025
3:00-5:00 pm MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ
#NRG2025

Session Co-Chairs

Michael Birrer, MD, PhD
TSC Chair

Adam Dicker, MD
TSC Vice Chair

Vered Stearns, MD
TSC Vice Chair

Presenters

Erin Stewart, PhD
Artera

Precision Medicine in Pixels: Prognostic & Predictive AI-derived Digital Pathology Biomarkers

Travis Parke Schrank, MD, PhD
University of North Carolina

Highly Distinct Molecular Subtypes of HPV+ HNSCC - Potential for Personalized Therapy

Doris Benbrook, PhD
University of Oklahoma

Drug Development in the Route 66 Endometrial Cancer SPORE

Fiona McAlister, PhD
Southern Oklahoma Technology Center

From Bench to Bedside - A Patient's Journey Translating Science into Survival

Session Title	Translational Science Committee		
Date	January 16, 2024	**Chair(s)**	Michael Birrer, MD, PhD; Adam Dicker, MD, PhD, Vered Stearns, MD
Time	3:00 – 5:00 pm MT	**Vice Chair(s)**	

Learning Objectives

Following this activity, participants will be better able to:

1. To understand the role of translational science in NRG-Oncology clinical trials
2. To understand translational science from a patient standpoint
3. To understand the potential of AI driven digital pathology

Meeting Agenda

Time	Topic	Presenter
3:00 – 3:05 pm	Welcome and Introductions	Michael Birrer, MD, PhD (University of Alabama)
3:05 – 3:30 pm	Precision Medicine in Pixels: Prognostic & Predictive AI-derived Digital Pathology Biomarkers	Erin Stewart, PhD (Artera)
3:30 – 3:55 pm	Highly Distinct Molecular Subtypes of HPV+ HNSCC - Potential for Personalized Therapy	Travis Parke Schrank, MD, PhD (University of North Carolina)
3:55 – 4:30 pm	Drug Development in the Route 66 Endometrial Cancer SPORE	Doris Benbrook, PhD (University of Oklahoma)
4:30 – 4:55 pm	From Bench to Bedside - A Patient's Journey Translating Science into Survival	Fiona McAlister, PhD (Southern Oklahoma Technology Center)
4:55 – 5:00 pm	Concluding Remarks	Michael Birrer, MD, PhD

Additional Notes:

Protocol Support Committee

Nurse / Clinical Research Associate
Continuing Educational Sessions

Friday, January 17, 2025
7:30 - 11:45 am MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ

Program Facilitators

Cynthia Licavoli, RN, BSN, MHA
Marissa Weiss, MBA
Jacqueline Ludwig, RN, BSN, CCRP

Presentations in-person & virtual

Introduction/Welcome	**Jacqueline Ludwig, RN, BSN, CCRP**
Panel Presentation: Mentorship & Colleague Retention	**Edward Bleta** **Devon Coleman, MS, CCRC** **Pamela Mason, RN, BSN, CCRP**
Early Onset Colorectal Cancer & the Microbiome	**Thomas George, MD, FACP, FASCO**
PMB & Aurora Updates	**Kayla Dye, PharmD**
Pathology 101	**Shannon Jones McCall, MD**
Panel Presentation: Onboarding New CRP	**Stacey Lewis, BSN, RN, OCN** **Tiffany Elsea, BA, CCRP** **Devon Coleman, MS, CCRC**
Questions, Closing Remarks, Evaluations	**Jacqueline Ludwig, RN, BSN, CCRP**

This nursing continuing professional development activity was approved by the Virginia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

Protocol Support Committee
Nurse/Clinical Research Associate Continuing Educational Sessions

Date:	**Friday, January 17, 2025**
Start and End Time:	**7:30 am MT – 11:45 am MT (presentations in-person & virtual)**
PSC Chair:	**Terry Thomas MS, CCRC**
PSC Vice Chairs:	**Nancy Fusco RN, BSN & Cynthia Licavoli RN, BSN, MHA**
Program Facilitators:	**Cynthia Licavoli RN, BSN, MHA, Marissa Weiss, MBA & Jacqueline Ludwig, RN, BSN, CCRP**

Learning Objectives
Following this activity, participants will be better able to:

1. Identify and discuss the NRG Oncology Mentorship Program and application process for Mentors and Mentees.
2. Identify and discuss how the mentorship program has engaged colleague retention.
3. Identify and discuss the national trends in the age migration of colorectal cancer and associated demographcs.
4. Identify and discuss the variety of risk factors that may contribute to increasing trends in colorectal cancer, particularly the potential role of the microbiome.
5. Discuss current PMB procedures and support services with updates for the AURORA system.
6. Identify and discuss the standard of care in pathology and identify best practices for research involving tissue.
7. Identify and discuss strategies and best practices for onboarding new clinical research professionals.

AGENDA

Time	**Presentation**	**Speakers**
7:30 am- 7:40 am	Introduction/Welcome	Jacqueline Ludwig, RN, BSN, CCRP
7:40 am- 8:10 am	Panel Presentation: Mentorship & Colleague Retention	Edward Bleta Devon Coleman, MS, CCRC Pamela Mason, RN, BSN, CCRP
8:10 am – 9:00 am	Early Onset Colorectal Cancer and the Microbiome	Thomas George, MD, FACP, FASCO
9:00 am – 9:25 am	PMB and AURORA Updates	Kayla Dye, PharmD
9:25 am – 9:40 am	**BREAK**	
9:40 am – 10:40 am	Pathology 101	Shannon Jones McCall, MD
10:40 am – 11:40 am	Panel Presentation: Onboarding New CRP	Stacey Lewis, BSN, RN, OCN Tiffany Elsea, BA, CCRP Devon Coleman, MS, CCRC
11:40 am – 11:45 am	Questions, Closing Remarks, Evaluations	Jacqueline Ludwig, RN, BSN, CCRP

This nursing continuing professional development activity was approved by the Virginia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.

NCORP Town Hall

Friday, January 17, 2025
10-11:30am MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ
#NRG2025

Session Co-Chairs

Deborah Bruner, PhD, RN
NCORP PI

Lisa Kachnic, MD
NCORP Co-PI

Deb Bruner, PhD, RN
NCORP PI

Welcome, NRG NCORP announcements
Recognition of Dr. Walker's NCORP leadership

Adam Raben, MD
ChristianaCare

Clinical Trial Enrollment in a Leading NCORP Institution

Erin Gillespie, MD
Fred Hutch Cancer Center

NRG-CC014/PREEMPT

Jeff Duecker, MD
University of Pittsburgh

NRG-CC005/FORTE Update

Brandy Heckman-Stoddard, MD
Acting Director
NCI Community Oncology Research Program

NCI NCORP Update

Kathleen Castro, RN, MS
Program Officer, Nurse Consultant, NCI Division of Cancer Control and Population Sciences

NCI CCDR Update

Session Title	NCORP Town Hall		
Date	January 17, 2025	**Chair(s)**	Deborah Bruner, PhD, RN; Lisa Kachnic, MD
Time	10:00 – 11:30amMT	**Vice Chair(s)**	

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss proposed and ongoing NRG NCORP research trials.
2. Apply procedures and best practices to implement a protocol within NCORP.
3. Learn about opportunities in CCDR and CPC clinical trials.

Meeting Agenda

Time	Topic	Presenter
10:00 – 10:15am	Welcome, NRG NCORP announcements Recognition of Dr. Walker's NCORP leadership	Deb Bruner, PhD, NCORP PI
10:15 – 10:30am	Clinical Trial Enrollment in a Leading NCORP Institution	Adam Raben, MD
10:30 – 10:35am	Q&A/Discussion	
10:35 – 10:45am	NRG-CC014: Radiation Therapy for High-Risk Asymptomatic Bone Metastases: A Pragmatic Multicenter Randomized Phase 3 Clinical Trial (PREEMPT)	Erin Gillespie, MD
10:45 – 10:50am	Q&A/Discussion	
10:50 – 11:00am	NRG-CC005/FORTE update	Jeff Dueker, MD
11:00 – 11:10am	NCI NCORP Update	Brandy Heckman-Stoddard, MD, Acting Director, NCI Community Oncology Research Program
11:10 – 11:20am	NCI CCDR Update	Kathleen Castro, RN, MS, Program Officer, Nurse Consultant, NCI Division of Cancer Control and Population Sciences
11:20 – 11:30am	Questions / Discussion	

General Session

Friday, January 17, 2025
12:00-1:00 pm MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ

#NRG2025

Session Co-Chairs

Robert Mannel, MD
NRG Group Chair

Quynh-Thu Le, MD
NRG Group Chair

Norman Wolmark, MD
NRG Group Chair

Presenters

Robert Mannel, MD
NRG Group Chair
Group Updates & Highlights

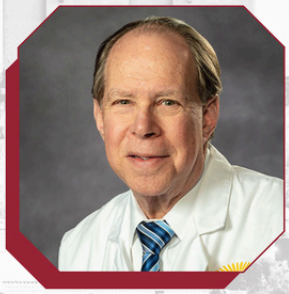
Mitchell Machtay, MD
NRG Deputy Group Chair
Research Center Update

James Dignam, PhD
Group Statistician
SDMC Update

David Miller, MD
NRG Deputy Group Chair
Membership Update

Deborah W. Bruner, RN, PhD
NRG NCORP PI
NCORP Research Base Update

Jeffry Simko, MD, PhD
Biospecimen Bank PI
Biospecimen Bank Update



Harry Bear, MD
NRG Deputy Group Chair
Publications & Communications Update

Session Title	General Session		
Date	January 17, 2024	**Chair(s)**	Robert Mannel, MD, Quynh-Thu Le, MD, Norman Wolmark, MD
Time	12:00 – 1:00pm MT	**Program Facilitator**	Robert Mannel, MD

Meeting Agenda

Time	Topic	Presenter
12:00 – 12:15pm	**Welcome, Group Updates, and Highlights**	Robert Mannel, MD, NRG Oncology Group Chair
12:15 – 12:20pm	**NRG Research Center Update**	Mitchell Machtay, MD, NRG Oncology Deputy Group Chair
12:20 – 12:25pm	**NRG Membership Update**	David Miller, MD, NRG Oncology Deputy Group Chair
12:25 – 12:30pm	**NRG Statistics and Data Management Center (SDMC) Update**	James Dignam, PhD, NRG Oncology Group Statistician
12:30 – 12:35pm	**NRG NCORP Research Base Update**	Deborah Watkins Bruner, RN, PhD, NRG NCORP PI
12:35 – 12:40pm	**NRG Biospecimen Bank Update**	Jeffry Simko, MD, PhD, NRG Oncology Biospecimen Bank PI
12:45 – 12:50pm	**NRG Publications & Communications Update**	Harry Bear, MD, PhD, NRG Oncology Deputy Group Chair
12:50 – 1:00pm	**Questions & Closing Remarks**	Robert Mannel, MD, NRG Oncology Group Chair

Scientific Session

Friday, January 17, 2025
3:00-4:30 pm MT

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ
#NRG2025

Session Co-Chairs


Robert Mannel, MD


Quynh-Thu Le, MD


Norman Wolmark, MD


James Dignam, PhD

Presenters


Robert Mannel, MD — NRG Oncology Gold Medal Award
Introduction - Embracing the Unexpected in Clinical Trials


Sue Yom, MD — NRG-HN005 – De-escalation of RT Dose in Good Prognosis H&N


Charles Geyer, MD — NRG-BR004 – Safety Challenges in HER2+ Breast Cancer


Andrew Lassman, MD — NRG-BN007 – RT + Dual Immunotherapy vs. Standard of Care in Glioblastoma


James Dignam, PhD — Statistical Insights on Trial Outcomes

Panel Discussion – From P-values to Practice


Jame Abraham, MD


Chen Hu, PhD


Mitchell Machtay, MD

Session Title	Scientific Session – *Unexpected Triumphs: Finding Value in the Unforeseen*		
Session Chairs	Robert Mannel, MD, Quynh-Thu Le, MD, Norman Wolmark, MD, James Dignam, PhD		
Date	January 17, 2025	**Location**	West 301D

Learning Objectives

Following this activity, participants will be better able to:

1. **Understand Trial Design and Interpretation**
   - Identify key design strategies, such as phase II/III trials, and their role in minimizing risk and optimizing resource allocation in clinical research.
   - Recognize the implications of unexpected or equivocal findings in clinical trials and how these contribute to broader scientific understanding.
2. **Evaluate the Role of Predictive Biomarkers**
   - Discuss the risks associated with relying on unvalidated biomarkers as predictive tools in clinical trial designs.
   - Analyze lessons from NRG-BN007 regarding the limitations and potential pitfalls of omitting standard therapies based on provisional biomarker data.
3. **Appreciate Challenges in Noninferiority Trials**
   - Distinguish between the objectives and challenges of noninferiority and superiority trials, particularly in therapeutic de-escalation studies like NRG-HN005.
   - Explore strategies for interpreting and defending noninferiority trial outcomes, especially when they contradict community expectations or established practices.
4. **Address Ethical and Practical Considerations in Safety Monitoring**
   - Examine the importance of pre-established safety monitoring protocols to guide interim analyses and avoid premature trial termination, as highlighted in NRG-BR004.
   - Balance ethical obligations to patient welfare with the scientific integrity of clinical trials.
5. **Integrate Lessons Across Trials**
   - Synthesize insights from multiple trials (e.g., NRG-BN007, NRG-HN005, NRG-BR004) to inform best practices in clinical research design, execution, and communication of results.
   - Consider the broader implications of trial outcomes for both clinical practice and research strategy.
6. **Reflect on Unexpected Outcomes and Future Planning**
   - Discuss how unexpected trial outcomes, even those that challenge prevailing assumptions or practices, can inform future trial designs and research priorities.
   - Evaluate whether the current approach to large, low-event-rate trials aligns with organizational and scientific goals, considering examples from NRG trials.

Meeting Agenda

Time	Topic	Presenter
3:00 – 3:10pm	**NRG Oncology Gold Medal Award**	Robert Mannel, MD
3:10 – 3:15pm	**Introduction - Embracing the Unexpected in Clinical Trials**	Robert Mannel, MD
3:15 – 3:30pm	**NRG-HN005 – De-escalation of RT Dose in Good Prognosis H&N** **Key Topics**: Challenges of noninferiority design, lessons from unexpected findings, and implications for therapeutic strategies.	Sue Yom, MD
3:30 – 3:45pm	**NRG-BR004 – Safety Challenges in HER2+ Breast Cancer** **Key Topics**: Balancing patient safety with trial integrity, and interpreting results in the context of ethical research practices.	Charles Geyer, MD
3:45 – 4:00pm	**NRG-BN007 – RT + Dual Immunotherapy vs. Standard of Care in Glioblastoma** **Key Topics:** Lessons from bold trial designs, including the risks of relying on provisional biomarker data. The importance of phase II/III designs in mitigating risks and addressing endpoints effectively.	Andrew Lassman, MD
4:00 – 4:05pm	**Statistical Insights on Trial Outcomes**	James Dignam, PhD
4:05 – 4:30pm	**Panel Discussion – From P-values to Practice**	**Panelists:** Jame Abraham, MD Chen Hu, PhD Mitchell Machtay, MD

Communications & Digital Engagement Workshop

Virtual Session

formerly Social Media Workshop

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ
#NRG2025

Monday, January 13, 2025
11am-12pm MT
1-2pm ET

RECORDING AVAILABLE

Session Co-Chairs

Kristin Higgins, MD
City of Hope

Miriam Knoll, MD, DABR
Northshore LIJ

Presenters

Eli Sapir, MD
Chair, Radiation Oncology Institute at Samson Assuta Ashdod University Hospital
Chair, Israeli National Radiation Oncology Group

Orit Gutfeld, MD
Chair, Radiation Oncology Tel Aviv Sourasky Medical Center

International Engagement in Radiation Oncology

Lauren Henke, MD
University Hospitals
Case Western Reserve University

The NRG Oncology Podcast Update

Kristin Higgins, MD
City of Hope

NRG Oncology PI Toolkit Update

Session Title	Communications & Digital Engagement Workshop (formerly Social Media) Virtual Session		
Date	January 13, 2025	**Co-Chair**	Kristin Higgins, MD
Time	11am-12pm MST	**Co-Chair**	Miriam Knoll, MD

Learning Objectives

Following this activity, participants will be better able to:

1. To understand the paradigm shifts in oncology using online engagement and digital communications tools, including social media.
2. To understand the importance of patient advocacy using online engagement and digital communications tools.
3. To gain knowledge on how online outreach helps with clinical trial recruitment.

Meeting Agenda

Topic	Presenter
Welcome & Introductions	
International Engagement in Radiation Oncology	Eli Sapir, MD & Orit Gutfeld, MD ISTRO Co-Chairs
The NRG Oncology Podcast update	Lauren Henke, MD
NRG Oncology PI Toolkit update	Kristin Higgins, MD

Additional Notes: Digital engagement tools are increasingly used by physicians and patients. Over the past few years, many paradigm shifts in medicine have been facilitated via online discussions. This panel will discuss how communications using digital engagement tools, including social media, help with clinical trial recruitment from both the physician and patient perspective.

NRG ONCOLOGY

CME/Non-CME Agendas

#NRG2025

Session Information

Session Title	NRG Adaptive RT Working Group Virtual Meeting Agenda		
Date	January 14, 2025	Chair(s)	Hyun Kim, MD
Time	1:00 – 2:30pm ET 12:00 –1:30pm CT 11:00am–12:30pmMT	Vice Chair(s)	Adam Yock, PhD
Room Location	Virtual Only – via Zoom meeting link		

Meeting Agenda

Eastern Times listed below	Topic	Presenter
1:00 – 1:05pm	Welcome, Introductions • Working Group Updates • Held zoom meetings - Sept. 19th and Nov. 21st • Presentation at NRG Radiation Oncology Committee Meeting – In Person only – Friday, Jan. 17th at 8:05 am – 8:45 am Mountain Time • **"The State of Adaptive RT: Current Technology and Upcoming Clinical Trials"**	Hyun Kim, MD Adam Yock, PhD
1:05 – 1:15pm	<u>Goals/Objectives</u> • Clinical focus • Generate adaptive RT protocol templates • Resource for developing clinical trials / PIs • Disease Site Representatives	Hyun Kim, MD Adam Yock, PhD
1:15 – 1:45pm	• <u>Update on Adaptive Template Components</u>	Hyun Kim, MD Adam Yock, PhD
1:45 – 2:00pm	<u>Industry Roundtable</u> • Set up in person/hybrid meeting with interested industry partners • Discuss how we can collaborate and give input on how they drive their technology	All
2:00 – 2:25pm	• <u>Disease Sites</u> GYN	

	GU CNS Lung H & N Breast GI – Colorectal GI – Non-Colorectal	
2:25pm	Other Business: Questions/ General Discussions	
2:30pm	Adjournment	

Session Title	NRG-BR008 Workshop Agenda
Date	January 18, 2024
Time	8:00 am – 9:00 am MT

Meeting Agenda

Time	Topic	Presenter
8:00 - 8:05 am	Welcome	Lior Z. Braunstein, MD / Melissa Mitchell, MD
8:05 – 8:15 am	NRG- BR008 Background and protocol overview	Lior Z. Braunstein, MD
8:15 – 8:25 am	Protocol eligibility and treatment information	Melissa Mitchell, MD
8:25 – 8:35 am	BR008 proposed amendments	Lior Z. Braunstein, MD / Melissa Mitchell, MD
8:35 – 9:00 am	Questions & Answers	

Additional Notes:

Session Title	NRG-BR009 Workshop		
Date	January 18, 2025	**Chair(s)**	Eleftherios Mamounas, MD, MPH
Time	7:00 am – 8:00 am	**Vice Chair(s)**	

Meeting Agenda

Time	Topic	Presenter
7:00am – 7:10am	Welcome and NRG-BR009 Background	Eleftherios Mamounas, MD, MPH
7:10am – 7:25am	NRG-BR009 Protocol Eligibility and Treatment Overview	Shannon Puhalla, MD
7:25am – 7:40am	NRG-BR009 Protocol Overview and Estradiol Measurement Issues	Sandra Swain, MD
7:40am – 7:50am	NRG-BR009 Quality of Life and OFSET Registry	Sandra Swain, MD
7:50am – 8:00am	Question and Answers and Open Discussion	

Additional Notes:

Session Title	Canadian Subcommittee Meeting		
Date	January 16, 2025	**Chair(s)**	Al Covens, MD
Time	11:00am – 12:00pmMT	**Vice Chair(s)**	Christina Tsien, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing NRG Oncology clinical trials available in Canada
2. Discuss and subsequently apply standards and procedures required to participate in a research protocol supported by NRG Oncology
3. Learn about trials available in Canada

Meeting Agenda

Time	Topic	Presenter
11:00 – 11:10am	Welcome, Introductions Disease site liaison update NRG trials open to accrual in Canada Comments/questions for NRG Group Chairs	Al Covens, MD; Christina Tsien, MD; Erica Field
11:10 – 11:20am	Protocol NRG-GI012: Phase III Randomized Trial of Systemic Treatment +/- Liver SBRT in Hepatocellular Cancer with Macrovascular Invasion (HELIO-RT)	Jennifer Wo, MD, NRG-GI012 Study Chair
11:20 – 11:25am	Discussion/Questions	
11:25 – 11:35am	NRG Genitourinary (GU) committee updates	Paul Nguyen, MD, NRG Genitourinary Committee Chair
11:35 – 11:45am	NRG Head and Neck committee updates	Sue Yom, MD, NRG Head and Neck Committee Chair
11:45 – 11:55am	NRG-CC009: Phase III Trial of Stereotactic Radiosurgery (SRS) versus Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) for Brain Metastases from Small Cell Lung Cancer	Vinai Gondi, MD
11:55am – 12:00pm	Discussion/Questions	

Session Title	Cancer Care Delivery Research Committee meeting		
Date	January 16, 2025	**Chair(s)**	Mary Cooley, PhD
Time	12:00 – 1:30pm MT	**Vice Chair(s)**	

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss proposed and ongoing NRG cancer care delivery research trials.
2. Discuss proposed and ongoing NRG cancer care delivery research trials and cross-cutting aims with disparities.
3. Identify and prioritize areas of unmet need in cancer care delivery research.

Apply procedures required to design, submit and implement a research protocol for support by the NRG.

Meeting Agenda

Time	Topic	Presenter
12:00 – 12:10pm	Welcome, introductions and announcements	Mary Cooley, PhD
12:10 – 12:25pm	Strategies for Recruitment and Retention of Diverse and Underserved Cancer Survivor and Caregiver Dyads in Clinical Trials	Terry Badger, PhD; Molly Hadeed, MPA
12:25 – 12:30pm	Questions/discussion	
12:30 – 12:45pm	NRG-CC012CD: Managing Symptoms and Psychological Distress During Oral Anti-Cancer Treatment – Study Update	Tracy Crane, PhD
12:45 – 12:50pm	Questions/discussion	
12:50 – 1:05pm	Physical Activity Monitoring to Enhance Supportive Care During Concurrent Chemoradiotherapy for Locally Advanced Non-small Cell Lung Cancer: A Randomized Trial	Julian Hong, MD; Nitin Ohri, MD
1:05 – 1:10pm	Questions/discussion	
1:10 – 1:25pm	NRG-CC007CD: Increasing the Dose of Survivorship Care Planning in Prostate Cancer Survivors Who Receive Androgen Deprivation Therapy – Study Update	Ron Chen, MD
1:25 – 1:30pm	Questions/discussion	

Session Title	Cancer Prevention and Control Committee Meeting		
Date	January 16, 2025	**Chair(s)**	Lisa Kachnic, MD; Julie Bauman, MD
Time	1:45 – 3:15pm MT	**Vice Chair(s)**	Tracy Crane, PhD; Stephanie Blank, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss ongoing and proposed NRG clinical trials on cancer prevention and control.
2. Discuss strategies for recruitment and enrollment of diverse populations.
3. Discuss multi-disciplinary aspects of ongoing and proposed clinical trials in each of the primary disease sites.
4. Identify and prioritize areas of unmet need in cancer prevention and control research in each of the primary disease sites.
5. Identify and discuss the results and publication status of NRG CPC clinical trials recently completed.
6. Apply procedures required to design, submit and conduct a research protocol for support by NRG.

Meeting Agenda

Time	Topic	Presenter
1:45 – 2:00pm	Welcome, Introductions, Announcements, Overview of open and developing NRG CPC trials	CPC Chairs
2:00 – 2:15pm	NRG-CC013: A Randomized, Masked, Placebo Controlled, Phase II Trial Of Concurrent Chemoradiation With BMX-001 In Patients With Head And Neck Squamous Cell Carcinoma Receiving Concurrent Chemoradiation	Sue Yom, MD; Carryn Anderson, MD
2:15 – 2:20pm	Questions/Discussion	
2:20 – 2:35pm	NRG-CC014: Radiation Therapy for High-Risk Asymptomatic Bone Metastases: A Pragmatic Multicenter Randomized Phase 3 Clinical Trial (PREEMPT)	Erin Gillespie, MD
2:35 – 2:40pm	Questions/Discussion	

2:40 – 2:55pm	NRG-CC015: Harnessing E-Mindfulness Approaches for Living-After Breast Cancer (HEAL-ABC)	Julienne Bower, PhD
2:55 – 3:10pm	NCORP pilot project: Virtually Delivered Home-based Exercise Intervention on Cognitive Impairment and Gut Microbiome in Adolescent and Young Adult Brain Tumor Survivors: A Pilot Randomized Controlled Trial.	Jingbing Bai, PhD
3:10 – 3:15pm	Questions/Discussion	

Session Title	Cervical and Vulvar Cancer Committee Meeting		
Date	January 17, 2025	**Chair(s)**	Charles A. Leath, III
Time	8:00 – 10:00 am MST	**Vice Chair(s)**	Jyoti Mayadev; Dmitry Zamarin

Learning Objectives

Following this activity, participants will be better able to:

1. Review recent knowledge gained in treating cervical cancer
2. Discuss organization, planning and completion of the GCIG Consensus Conference
3. Reviewed current gaps in NCI cervical cancer portfolio and ways to address

Meeting Agenda

Time	Topic	Presenter
8:00 – 8:15	**Introduction / Announcements** a. Welcome, committee membership and rotation plan and review of July 2024 minutes i. Annual rotation of approximately 10% from CORE committee b. Cervix updates from the task forces/Patient Advocate i. Cervical Cancer Task Force – Leslie Boyd ii. Cervical cancer patient advocate – Kimberly Williams	
8:15 – 8:30	**Educational Session** c. GCIG Cervical Cancer Consensus Mtg Review (Michael Bookman)	
8:30 – 8:45	**Discussion** d. GCIG Cervical Cancer Consensus Mtg Review (Michael Bookman)	
8:45 – 9:15	**New Concepts** **PI2506** Phase I/IB trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with or without a PARPi talazoparib in advanced/recurrent cervical carcinoma. Anne Van Arsdale/ Nicole Nevadunsky)	
9:15 – 9:45	Previously committee approved/reviewed concepts – current updates and future directions CV2332: A Phase I/II randomized non inferiority trial of hypofractionated IMRT with concurrent cisplatin and brachytherapy for cervical cancer versus conventional standard of care. (Henson/Moore/Mayadev)	

DISCUSSION with committee re disapproval comments

CV2305: STRIVE Study: STRatification of Vulvar squamous cell carcinoma by HPV and p53 status to guide Excision. (McAlpine/Jamieson : CCTG Salani/Gien : NRG)

Dual mTOR and Immune Checkpoint Inhibition as a Strategy for Recurrent Cervical Cancer (TORIC): A Phase I/II Study of Sapanisertib plus Pembrolizumab. (Fernanda Musa)

CV2432 Randomized phase II trial of the HER2 targeting Antibody Drug Conjugate, Trastuzumab deruxtecan versus Tisotumab vedotin (TV) in recurrent, HER2 1+ or 2+ cervical cancer previously treated or ineligible for immune checkpoint inhibitors – (Christina Washington)

9:45 – 9:55

Concepts in Development; Brief updates

- NRG GY037 (formerly CV2401) Immune priming with neoadjuvant immunotherapy and chemotherapy vs. chemoradiation followed by immunotherapy for LACC (Mayadev, Zamarin) : CTEP approval
- CV2346 Chemoradiation with or without Checkpoint Inhibition in Lymph Node Positive Carcinoma of the Vulva. (Scott Glaser) Previously **CV1964: to RS**

9:55 – 10:00

Operational management on-going NRG trials

D. Closed Studies

Protocols: 101, 120, 205, 222, 141, 173, 179, 204, 206, 240, 233, 279, 9806

E. Active / Recently Completed Trials

a. **NRG-GY024** Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Slomovitz) N=157

b. **GOG-0724/RTOG0724**: Phase III trial randomized study of concurrent chemotherapy and pelvic RT with or without adjuvant chemotherapy in high-risk patients with early stage cervical carcinoma following radical hysterectomy. (Heidi Gray, Anuja Jhingran)

i. Opened April 2009
ASCO presentation 2024
Manuscript in preparation

c. **GOG-0263**: Randomized clinical trial for adjuvant chemoradiation in post-operative cervical cancer patients with intermediate risk factors (Sang Young Ryu, Kevin A)

i. Opened April 2010
ii. Amended Nov 2017 to decrease accrual from 534 to 360
iii. Closed
iv. Accrual 339/360 (94.2%)
Final analysis March 2024 (2 yrs post final accrual as the events are very slow)

d. **GOG-0278**: Evaluation of physical function and quality of life (QOL) before and after non-radical surgical therapy for stage IA1-IB1 (≤2cm) cervical cancer. (Al Covens)

i. Opened October 1, 2012
ii. PET imaging amendment approved July 2015

iii. Accrual 220/220 (100%)
SGO 2024 Presentations
Manuscript in preparation

e. **GOG-0279**: A phase II trial evaluating cisplatin and gemcitabine concurrently with intensity-modulated radiation therapy (IMRT) for the treatment of locally advanced squamous cell carcinoma of the vulva. (Neil S. Horowitz)
   i. Opened July 2, 2012
   ii. Temporarily Closed June 15,2015 after enrolling 28 in 1st stage
   iii. 2nd stage re-opened July 2016
   iv. Accrual completed
   Final analysis report completed May 2022
   Published JCO
   To be terminated

f. **NRG-GY006**: A randomized phase II trial of radiation therapy and cisplatin alone or in combination with intravenous triapine in women with newly diagnosed bulky stage IB2, stage II, IIIB, or IVA Cancer of the uterine cervix or Stage II-IVA vaginal cancer. (Trey Leath, Loren Mell)
   i. Opened January 15, 2016
   ii. Amendment to CTEP re: increase in accrual size and transition to Randomized phase 3
   iii. Temporarily closed secondary to drug shortage May 28, 2021
   iv. Accrual complete
   v. Primary MS in review

g. **NRG-GY017**: Phase I trial using anti PD-L1 (atezolizumab) as immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer. (Jyoti Mayadev)
   i. Opened October 26, 2018
   ii. Accrual: 40/40
   iii. Presentation SGO 2022 and SGO 2023; final analysis report to be performed Oct 2022
   iv. Primary MS accepted Nature Communications Dec 2024

F. Previously Rejected Concepts
   a. Committee Level
      i. CONTESSA (Cobb) – Fertility sparing surgery
      ii. CERVANTES (GCIG) – Follow-up to Sedlis with radical surgery and adjuvant therapy
      iii. CV1948 – Radical hysterectomy via LSC vs. Xlap (Davidson)
      iv. CV2062 (Wiebe) – PROS – not approved based on design
      v. CV2133 (Mayadev / Mell) – Durvalumab in place of CDDP for platinum ineligible patients
      vi. CV2226 (Frumovitz) – PAROLA – PA lymphadenectomy study

vii. KGOG 1047 (Roh) – Debulking lymphadenectomy study
viii. CV2333 (Rose) – A18 Replacement

G. CV2407 (Lea/Miller) – A Phase III Randomized Three Arm Trial of Concurrent chemoradiation or Pembrolizumab and concurrent chemoradiation or Induction Chemotherapy followed by concurrent chemoradiation in locally advanced cervical cancer: Lea to join NRG 037 for induction chemotherapy and CRT/IO.

i.

b. GCSC Level
   i. CV1963 - Randomized Phase II Trial of Ablative Radiation Therapy for Women with Oligometastatic Recurrent Cervical Cancer (Taunk/Chino)
   ii. CV2220 - A Randomized Phase II Study of the Integration of Hypofractionated Image-Guided Pelvic Radiotherapy Into Chemotherapy and Pembrolizumab/Bevacizumab in Newly Diagnosed Stage IVB Cervical CancerStage IVB ChemoRT (D. Chase)
   iii. CV2040 (Leung) – SPARTACUS II
   iv. PI1915 (Moxley) – PARP+ATR – Not supported by CTEP.
   v. PI2136 (Moxley) – PARP+ATR – Not supported by CTEP/Drug Sponsor

c. Other
   i. CV1912 (Lin) – Nelfinavir+CRT for locally advanced vulvar cancer – Not on CRADA
   ii. DT2013 (Doll) – Glutaminase inhibitor with CRT for node positive LACC – Compound abandonded by sponsor
   iii. CV1922 (Salani) – Maintenance strategies after GOG 240 Therap. Not supported by Pharma.
   iv. DT2059 (Henson) Hypofractionated RT with M3814 and avelumab – Agent abandonded by company
   v. CV2143 (Salani) – Substitution of TV for paclitaxel with Platinum, Pembrolizumab a+/- bevacizumab – TV not on CRADA and not supported
   vi. CV2218 (Salani) – Addition of Tiragolumab and Atezo vs. Physicians's choice chemotherapy

H. Reports from Other Committees and Groups

a. Publications Subcommittee
b. Patient Centered Outcomes Research Committee
c. Ancillary Data Committee
d. Cancer Prevention and Control
e. Rare Tumor Committee
f. Vaccine Subcommittee
g. Pathology Committee
h. Radiation Committee
i. SPORE Committee
j. Nursing
k. Medical Oncology
l. Patient/Community/Advocacy

	I. Concluding Remarks and Wrap-up	

Additional Notes:

Session Title	Developmental Therapeutics Committee		
Date	January 16, 2025	**Chair(s)**	Roisin O'Cearbhaill, MD (Dev. Therapeutics) Panagiotis Konstantinopoulos (Dev. Therapeutics / Translational Research Chair) Stephanie Gaillard, MD, PhD (Phase I)
Time	12:30 – 2:30pm	**Vice Chair(s)**	Bradley Corr, MD (Phase I) Floor Backes, MD (Phase II)

Learning Objectives

Following this activity, participants will be better able to:

1. Participants will become familiar with the current status of translational research projects involving phase I and II studies that are under development or activated for accrual.
2. Participants will become familiar with the early identification and management of immunotherapy-related toxicities.
3. Clinical data related to novel investigational agents will be reviewed.
4. Recommendations for action by the GYN Developmental Therapeutics committee will be summarized.

Meeting Agenda

Time	Topic	Presenter
12:30 – 12:35	**Introduction**, Welcome. Review of opportunities for new investigators and discuss committee rotation.	Dr. Gaillard, Dr Corr, and Dr Backes
12:35 – 12:50	**Education**, The role of the Patient advocate in protocol development	Dr. Fiona McAlister
12:50 – 1:30	**Review DT new concepts** **Review for other committees**	TBD TBD
1:30 – 2:00	**Presentation of open active studies** GY022, GY031, GY034, ComboMATCH (EAY191-N4, EAY191-N4, EAY191-A3, EAY191-S3) **Update on studies under development:** **NRG-GY034** A Randomized Phase 1/2 Trial Evaluating the Addition of Tolinapant to Weekly Paclitaxel with or without	

	Bevacizumab in Patients with Recurrent Epithelial Ovarian Cancer (Zeligs/Annunziata/Moore) n=88 • CIRB final approval received 7/11. Opening soon **DT2430** Dual mTOR and Immune Checkpoint Inhibition as a Strategy for Recurrent Cervical Cancer (TORIC): A Phase I/II study of sapanisertib plus pembrolizumab (Musa/Moore) • Call with IDB 10/08/24 • Research Strategy Meeting January	
2:05 – 2:25	Education, Pharmacokinetics and Drug Drug Interaction Considerations for NRG early phase studies	Jan Beumer, PharmD PhD
2:25 – 2:30	Open discussion, closing remarks.	

Additional Notes:

<u>List of Studies</u>

Active PK Studies:

- **NRG-GY022**, Assessment of carboplatin clearance predictors: a companion PK study to NCI sponsored clinical trials or standard of care treatments using carboplatin (Sarah Taylor/Jan Beumer)
  - **289/350 enrolled**
  - **Open up to male participants only now**
  - **Video available to improve enrollment.**

Active Phase I Studies:

- **NRG-GY031** A Phase 1B Study of Combination ATR (M1774) and BET Inhibition (ZEN003694) to Exploit ARID1A Loss in Recurrent Ovarian and Endometrial Cancer (Andriani/Simpkins).
  - **Opened 8/31/23 ;** 13/60 enrolled
  - **Photophobia –** nighttime dosing in 2nd week of treatment, naps after dosing, sunglasses
  - **n/v:** Zofran prophylaxis 30 min prior (consider dex, olanzapine, rolapitant)
  - **Careful with prior severe myelosuppression**

- **NRG-GY034** A Randomized Phase 1/2 Trial Evaluating The Addition Of Astx660 (Tolinapant) To Weekly Paclitaxel With Or Without Bevacizumab In Patients With Recurrent Platinum Resistant And Platinum Refractory Epithelial Ovarian Cancer (Zeligs, Annunziata, Moore)
  - **Activation TBD**
  - Pending final approval letter from NCI to activate
  - **Planned accrual N=88**
    - **Phase I: N=6-36**
    - **Phase Ib: N=9+3**
    - **Phase II: N=88**

Safety lead-in

- **NRG-GY025** A randomized phase II trial of immunotherapy with dual immune checkpoint inhibitors compared to antiPD1 monotherapy in patients with deficient mismatch repair system recurrent endometrial carcinoma (Mahdi) – **currently open to all sites**
    - **28/90 patients enrolled (2nd safety lead-in: 25 in combo arm)**
    - Safety call every other Friday 3:00 pm
    - Measurable or evaluable disease; 0-2 prior lines (allowed to be chemo naïve)

Active Phase II Studies (including safety lead-ins):

- **EA191- N4** A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers: A ComboMATCH Treatment Trial (Westin)
    - Opened 3/6/23; **65/165 enrolled**
    - Assess for fatigue early, taking interruption and dose reduction sooner rather than later
    - Steroid and antibiotic creams on hand before rash starts. Intervene early (at grade 1) to avoid serious rashes.
    - Toxicity check per phone – 1-2 weeks in (4 week cycle)
    - Mandatory biopsy needed

- **EAY191-N5** A Randomized Trial of Neratinib, A Pan-ERBB Inhibitor, Alone or in Combination with Palbociclib, a CDK4/6 Inhibitor, in Patients with HER2+ Gynecologic Cancers and Other Solid Tumors: A ComboMATCH Treatment Trial (Mahdi)
    - Opened 2/12/24; enrolled 8/70
    - Plan to amend the protocol to allow prior ADC and other HER2 targeting (emailed Haider 12/6/24)

- **EAU191-A3:** Palbociclib and Binimetinib in RAS-Mutant Cancers (Shapiro and Liu)
    - Opened 11/15/2023
    - Current accrual 36/199
    - Includes low grade serous ovarian cancer

- **EAY191-S3:** Phase 2 Study of Paclitaxel (NSC #673089) + Ipatasertib (NSC #781451) in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors: A ComboMATCH Treatment Trial (Basho)
    - Opened 3/6/2023
    - Current accrual 8/33

Closed DT/Phase I studies:

Cervical Cancer Studies:

- **NRG-GY017** Anti PD-L1 (atezolizumab) as an immune primer and concurrently with extended field chemoradiotherapy for node positive locally advanced cervical cancer (Mayadev/ Schilder/Zamarin)
    - Plenary at SGO 2022 and 2023
    - Manuscript status update

Endometrial Cancer Studies:

- **NRG-GY014**, A phase II study of tazemetostat (EPZ-6438) in recurrent endometrioid or clear cell carcinoma of the ovary, and recurrent or persistent endometrioid endometrial adenocarcinoma (Eskander)
    - Presented at SGO 2024
    - Awaiting manuscript

- **GY028 (PTMA #100828)** Phase IB and randomized phase II trial of medroxyprogesterone acetate +/- ipatasertib in recurrent/metastatic endometrioid endometrial cancer (Onstad Grinsfelder/Westin)
    - Opened 1/13/23 ; Completed phase Ib
    - Reopened to phase II – now under Corpus committee

Ovarian Cancer Studies:

- **NRG-GY007** A phase I/II study of ruxolitinib with front-line neoadjuvant and post-surgical therapy in patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer (Landen) Completed accrual.
    - Presented at ASCO 2022, Published JCO Jul 2024.

- **NRG-GY009 (PTMA/CRDL)** A randomized, phase II/III study of pegylated liposomal doxorubicin and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab and atezolizumab versus pegylated liposomal doxorubicin/bevacizumab in platinum resistant ovarian cancer (O'Cearbhaill)
    - Phase II completed accrual May 2019. Phase III completed accrual October 2021
    - IGCS 2023

- **NRG-GY021** A randomized phase II trial of olaparib versus olaparib + tremelimumab in platinum-sensitive recurrent ovarian cancer (Adams)
    - Safety lead-in closed March 2021, study permanently closed
    - Toxicity limited further enrollment and analyzing data, manuscript pending
    - CMAC is doing correlative studies and completed.

- **GY027** Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Carboplatin and Paclitaxel with Ipatasertib in Epithelial Ovarian Cancer (Fuh/Moore)
    - Completed

Session Title	NRG Developmental Therapeutics Radiation Therapy Subcommittee		
Date	January 13, 2025	**Chair(s)**	Steven Lin, MD, PhD
Time	1-2:30 pm MT	**Vice Chair(s)**	Sandip Patel, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Understand the fundamentals of AI and radiomics: Participants will be able to describe the key concepts of artificial intelligence (AI) and radiomics, including how these technologies analyze medical imaging data to extract quantitative features that are relevant for patient diagnosis and treatment.
2. Explore the integration of AI and radiomics in clinical decision-making: Participants will learn how AI-driven radiomics can be used to enhance patient selection for personalized treatment plans, particularly in oncology, and evaluate its potential benefits in improving diagnostic accuracy and therapeutic outcomes.

Meeting Agenda

Time	Topic	Presenter
	Advancing Clinical Trials: Radiomics and Multiscale Machine Learning for Patient Selection and Stratification	Jia Wu, MD
	Disease Site and Working Group Updates:	
	Brain/CNS (Committee Liaison: Vinay Puduvalli, MD)	
	Genitourinary (Committee Liaison: Zachary Zumsteg, MD)	
	Head and Neck	
	Lung (Committee Liaison: Steven Lin, MD, PhD)	
	GI (non colorectal and colorectal) (Committee Liaison: Terence Williams, MD)	
	GYN (Committee Liaison: Jyoti Mayadev, MD)	
	Breast (Committee liaison: Steve Chmura, MD)	
	Sarcoma Working Group (Working Group Liaison: Meng Welliver, MD)	

Additional Notes:

Session Title	Early Career & New Investigator Committee – Educational Session: Roundtables		
Date	January 16, 2025	**Chair(s)**	Vinai Gondi, MD
Time	2:30 – 4:00 pm MT	**Vice Chair(s)**	Priya Rastogi, MD & Angeles Alvarez Secord, MD

Meeting Agenda

Time	Topic	Presenter
2:30 - 2:35pm	Welcome & Introductions	Vinai Gondi, MD
	Table 1 – Statistics	Kathryn Winter
	Table 2 – NCI Community Oncology Research Program (NCORP)	Erica Field & Deborah W. Bruner, RN, PhD
	Table 3 – Ancillary Projects	Steve Waggoner, MD
	Table 4 – Disease Site Committee Membership	Sue Yom, MD
	Table 5 – Patient Enrollment	Stephen Chun, MD
	Table 6 – Protocol Development (NRG HQ)	Nancy Soto
	Table 7 – Protocol Development Process	Kathleen Moore, MD
	Table 8 – Protocol Development Process	Minesh Mehta, MD
	Table 9 – Translational/Laboratory Research	Victoria Bae-Jump, MD, PhD & Katherine Fuh, MD, PhD
	Table 10 – Congressionally Directed Medical Research Programs	Sagar Ghosh, PhD, MBA
3:58 – 4:00pm	Closing Remarks	Vinai Gondi, MD

Additional Notes:

This session will be in person only.

Roundtable discussions will be 18-minute rounds every 20 minutes, providing 4 sessions for participants. Refer to the flyer/handout for the comprehensive list of presenters and table topics.

Please join us for the Networking Session immediately following from 4:00-5:00pm in the West 301AB foyer.

Gastrointestinal Cancer Committee Workshop Agenda

Date:	**Saturday, January 18, 2025**
Start and End Time:	**11:00 am - 12:30 pm MST**
Colorectal Chair:	**Thomas George, MD, FACP, FASCO**
Colorectal Co-Chair:	**Scott Kopetz, MD, PhD, FASCO**
Non-colorectal Chair:	**Ted Hong, MD**
Non-colorectal Co-Chair:	**David Ilson, MD**

Learning Objectives
Following this activity, participants will be better able to:

1. Appreciate the eligibility criteria and hypotheses being explored in current and upcoming GI Onc clinical trials

WORKSHOP AGENDA	**Discussion/Study Information**		**Speaker**
	Introduction and Opening Remarks, Announcements and Working Group updates		Ted Hong, MD Thomas George, MD
11:00	**CRC SUBCOMMITTEE - Review of Active and Select Upcoming NCTN Trials**		
NET		NCTN Portfolio of NET Studies	Heloisa Soares, MD
Adj. Colon	**NRG-GI008 (CIRCULATE-NA)**	ctDNA as decision tool for stage III colon cancer treatment	Arvind Dasari, MD
	A022004	BRAF V600E (MSS) colon adjuvant consolidation with Encorafenib & Cetuximab vs. BSC	Olatunji Alese, MD
mCRC	**NRG-GI004/S1610 (COMMIT)**	MSI-H mCRC 1L Immunotherapy Study	Caio Rocha Lima, MD
	S2107	Encorafenib & Cetuximab +/- Nivolumab in BRAFV600E mut (MSS) mCRC	Rimini Breakstone, MD
	EA2222	Systemic therapy +/- HAI following 1L therapy	Motaz Qadan, MD
	A022101/NRG-GI009 (ERASur)	Oligo mCRC Total Ablative Therapy	Paul Romesser, MD Kate Hitchcock, MD, PhD Eric Miller, MD, PhD
Rectal	**EA2201**	MSI-H rectal cancer Treatment w/ IO	Prajnan Das, MD
	A022104/NRG-GI010 (JANUS)	Watch & Wait vs. TME after optimal TNT	William Hall, MD Arvind Dasari, MD
	CCTG-032 (NEO-RT)	Neoadjuvant Chemo, Excision and Observation vs. ChemoRT for Early Rectal Cancer	Noam VanderWalde, MD
11:45	**NON-CRC SUBCOMMITTEE - Review of Active Trials and Select Upcoming NCTN Trials**		
Liver	**NRG GI012 (Trial in Development)**	Atezo/Bev +/- SBRT	Jennifer Wo
	NRG GI003	Phase III RCT of Protons vs. Photons for HCC	Ted Hong, MD
EGA	**NRG GI006**	Phase III RCT of Protons vs. Photons for Esoph Carcinoma	Steven Lin, MD
	NRG GI007	Phase I w/ Expansion Cohort of OBP-301 (Telomelysin) and Definitive ChemoRT for non-operative locally adv EGA	Geoff Ku, MD
	EA2183	Rand phase II evaluating consolidative radiation + IO during 1L systemic therapy in oligometastatic EGA	Kimberly Mak, MD
Anal	**EA2182**	A Randomized Phase II Study of De-intensified ChemoRT for Early-Stage Anal Squamous Cell Carcinoma (DECREASE)	Prajnan Das, MD
Panc	**NRG-GI011 (Trial in Development)**	A Phase III Randomized Trial of Dose Escalated Radiation in Locally Advanced Pancreatic Cancer (LAPC) Patients (LAP100)	Nina Sanford, MD

Session Title	Genitourinary Cancer Workshop Agenda		
Date	Saturday, January 18, 2025	**Chair(s)**	Paul Nguyen, MD
Time	7:30 AM – 9:00 AM MT	**Vice Chair(s)**	Jason Efstathiou, MD; Todd Morgan, MD; Oliver Sartor, MD, Phuoc Tran MD PhD
Program Facilitators	Paul Nguyen, MD		

Learning Objectives

Following this activity, participants will be better able to:

1. Recognize critical aspects of developing and conducting a clinical trial in genitourinary (GU) cancer therapy research in a cooperative group setting.
2. Identify and describe the design and status of new GU cancer clinical trials being planned and launched by NRG Oncology, to enable contribution to protocol design vetting and/or effective patient enrollment in newly-launched studies.
3. Identify and describe the status of ongoing GU cancer clinical trials being conducted by NRG Oncology, to enable effective patient enrollment in and treatment on these trials, and proper collection, submission and/or evaluation of the required patient data.
4. Identify, describe, and analyze aspects of ongoing NRG Oncology GU clinical trials which are in need of special support and improvement, to enable effective patient enrollment in and treatment on these trials, and proper collection, submission and/or evaluation of the required patient data.
5. Identify and discuss the results and publication status of GU cancer clinical trials recently completed by NRG Oncology, so they can make informed decisions based on the state of the science regarding patient treatment, and they can relay study results to patients treated on these trials.
6. Identify and describe new forms of radiotherapy delivery and their use in NRG Oncology GU cancer trials.
7. Identify and describe systemic therapies, including chemotherapeutic drugs, hormonal strategies, biologic agents, and new classes of targeted therapies that may be used in conjunction with radiation therapy in GU cancer treatment, and the effectiveness of those agents as demonstrated in NRG Oncology clinical trials.
8. Identify and describe new developments in biologic and imaging science that can be used in translational research strategies to identify GU cancer patient subgroups at risk for failure with existing treatments and identify new approaches for these patients.

Meeting Agenda

Time	Topic	Presenter
7:30-7:35	Opening Remarks and Update	Paul Nguyen, MD
7:35 – 8:50	NRG GU008: Androgen Deprivation Therapy With or Without Radiation Therapy or Docetaxel in Patients With Node-Positive Prostate Cancer: A Phase III Randomized Trial	Ronald Chen, MD, MPH

	NRG GU009 (PREDICT-RT): Parallel Phase III Randomized Trials for High Risk Prostate Cancer Testing Treatment De-Intensification for Men with Lower Genomic Risk and Treatment Intensification for Men with High Genomic Risk (PREDICT-RT)	Paul Nguyen, MD; Oliver Sartor, MD
	NRG GU010 (GUIDANCE): Genomic-Risk Stratified Unfavorable Intermediate Risk Prostate Cancer: De-intensification and Intensification Clinical Trial (GUIDANCE)	Neil Desai, MD; Ale Berlin, MD PhD
	NRG-GU011: Phase II trial of PROstate oligoMETastatic radiotHErapy with or without ANdrogen deprivation therapy (NRG PROMETHEAN)	Bridget Koontz, MD
	NRG GU012 (SAMURAI): Phase II **S**tereotactic **A**blative Radiation Therapy (SABR) For **M**etastatic **U**nresected **R**enal Cell C**a**rcinoma (RCC) Receiving **I**mmunotherapy ("SAMURAI")	Bill Hall, MD Rana McKay, MD
	EA8191: EA8191: Phase III Study of Local or Systemic Therapy Intensification Directed in Prostate Cancer Patients with Post-Prostatectomy Biochemical Recurrence (INDICATE)	Neha Vapiwala, MD Bridget Koontz, MD
	NRG GU013 (HIGH FIVE): Five fraction radiation for high-risk prostate cancer	Karen Hoffman, MD
8:50– 8:55	Translational Research	Phuoc Tran, MD PhD
	Medical Oncology Update	Oliver Sartor, MD
	Urology Update	Todd Morgan, MD
	New Business	Group

Additional Notes:

Session Title	Gynecologic Cancer Committee		
Date	January 18, 2025	**Chair(s)**	Carol Aghajanian, MD
Time	7:45 – 9:30 am	**Vice Chair(s)**	Paul DiSilvestro, MD David Gaffney, MD, PhD Heather Lankes, PhD, MPH (Translational Science Co-Chair)

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss the status and significance of new and ongoing clinical trials on the prevention, diagnosis, and treatment of gynecologic cancers.
2. Discuss promising translational research objectives and priorities for future clinical trials.
3. Apply standards and procedures required to design, submit, and conduct a research protocol for support by NRG Oncology.
4. Assure strict quality control of gynecologic cancer clinical trials.

Meeting Agenda

Time	Topic	Presenter
7:45	**I. <u>General Business</u>** a. Call to order b. Symposia updates	
	II. <u>Committee Descriptions</u> <u>Gynecologic Cancer Committee</u> **Cervix/Vulvar Cancer Subcommittee** • Cervical cancer – Randomized phase II, Phase II/III, Phase III • Vulvar cancer – Phase II, Randomized phase II, Phase II/III, Phase III **Ovarian Cancer Subcommittee** • Ovarian cancer (Ovarian cancer = Fallopian tube cancer, Ovarian cancer, Primary Peritoneal Cancer) ➢ Randomized phase II, Phase II/III, Phase III **Rare Tumor Subcommittee** • Clear Cell Tumors • Germ Cell Tumors • Mucosal melanoma • Ovarian - Low Grade Serous	

- Ovarian - Mucinous
- Ovarian - Stromal Tumors

Uterine Corpus Cancer Subcommittee

- Endometrial cancer
  - Randomized phase II, Phase II/III, Phase III
- Uterine sarcoma (leiomyosarcoma)
  - Randomized phase II, Phase II/III, Phase III
- Gestational trophoblastic neoplasm (GTN)

GYN Developmental Therapeutics Committee

- Early phase trials (Phase I, Phase I/II, Phase II), Window of opportunity trials
  - Cervical cancer
  - Endometrial cancer
  - Ovarian cancer
  - Uterine sarcoma

GYN Phase I Subcommittee

- Safety lead-ins
- Phase I

Other NCTN Group Trials & Study Champions

A091903, A Randomized Phase II Trial of Adjuvant Nivolumab with or Without Cabozantinib in Patients with Resected Mucosal Melanoma
Alliance: Alexander N. Shoushtari, MD
NRG Oncology: Danielle Vicus, MD

EAY191-A3, Palbociclib and Binimetinib in RAS-Mutant Cancers: A ComboMATCH Treatment Trial Alliance: Geoffrey Shapiro, MD, PhD, Joyce Liu, MD, Ardaman Shergill, MD
Cohort 1: Low Grade Serous Ovarian Cancer (LGSOC), MEK inhibitor naïve (KRAS/NRAS/HRAS, nonBRAF V600E actionable marker of interest or rare RAF fusions)
Cohort 2: Low Grade Serous Ovarian Cancer (LGSOC), progressed on prior MEK inhibitor (not genomically selected)
Cohort 3: Pancreatic Cancer harboring any KRAS/NRAS/HRAS, non-BRAF V600E actionable marker of interest or rare RAF fusions
Cohort 4: Tumor agnostic harboring any KRAS/NRAS/HRAS, nonBRAF V600E actionable marker of interest or rare RAF fusions, excluding LGSOC, NSCLC, colorectal cancer, pancreatic, and melanoma

EAY191-S3, Phase 2 Study of Paclitaxel (NSC #673089) + Ipatasertib (NSC #781451) in Taxane-Refractory Participants with AKT-Altered Advanced Non-Breast Solid Tumors: A ComboMATCH Treatment Trial SWOG: Reva Basho, MD, Haider Mahdi, MD, MPH

S2012, Randomized Phase II/III Trial of First Line Platinum/Etoposide with or Without Atezolizumab (NSC#783608) in Patients with Poorly Differentiated Extrapulmonary Small Cell Neuroendocrine Carcinomas (NEC)
NRG Oncology Study Champion: Mahdi

AGCT1531, A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors. **This is an Adolescent and Young Adult (AYA) Study: Available to COG and the Adult Groups**
NRG Oncology Study Champion: Covens

AGCT1532, A Randomized Phase 3 Trial of Accelerated Versus Standard BEP Chemotherapy for Patients with Intermediate and Poor-Risk Metastatic Germ Cell Tumors. **This is an Adolescent and Young Adult (AYA) Study: It is available to COG and the Adult Groups**
NRG Oncology Study Champion: Covens

III. **Cervix/Vulvar Cancer Subcommittee**

New Concepts

a. **PI2506**, Phase I/IB trial evaluating the safety and efficacy of BET inhibitor, ZEN003694 with or without a PARPi talazoparib in advanced/recurrent cervical carcinoma (Anne Van Arsdale/ Nicole Nevadunsky)

Studies Under Development

a. **NRG-GY037**, Neoadjuvant Pembrolizumab and Chemotherapy vs Chemoradiation and Pembrolizumab both followed by Pembrolizumab Maintenance for High Risk Locally Advanced Cervical Cancer (Jyoti Mayadev, Dmitriy Zamarin, Tashana Meyers, Kimberly Williams)
b. **CV2305**, STRIVE Study: STRatification of Vulvar squamous cell carcinoma by HPV and p53 status to guide Excision (Jessica McAlpine/Amy Jamieson: CCTG, Ritu Salani/Lillian Gien: NRG)
c. **CV2346**, Chemoradiation with or without Concurrent and Adjuvant Checkpoint Inhibition in Lymph Node Positive Carcinoma of the Vulva (Scott Glaser)
d. **DT2430**, DT2430 Dual mTOR and Immune Checkpoint Inhibition as a Strategy for Recurrent Cervical Cancer (TORIC): A Phase study of sapanisertib plus pembrolizumab (Fernanda Musa, Katy Moore) CRDL
e. **CV2432**, Randomized Phase II trial of the HER2 targeting Antibody Drug Conjugate, Trastuzumab deruxtecan versus Tisotumab vedotin (TV) in recurrent, HER2 1+ or 2+ cervical cancer previously treated or ineligible for immune checkpoint inhibitors (Christina Washington)

Active Studies:

a. **NRG-GY024**, Groningen International Study on Sentinel Nodes in Vulvar Cancer (GROINSS-V) III: A Prospective Phase II Treatment Trial (Brian Slomovitz)

Closed Studies, primary manuscript NOT published (Cervix): RTOG-0724, GOG-0263, NRG-GY006
Closed Studies, primary manuscript NOT published (DT):

Closed studies, primary manuscript published (Outside Group): 270 (GROINSS-V), THE OUTBACK TRIAL (ANZGOG 0902/GOG 0274/RTOG 1174)
Terminations:
Biospecimen Access:
MP2PRT (Tewari, GOG-0240)
Nav1601/CSC0135 (Secord, GOG-0240)
NRG-GY-TS030/CSC0213 (Mayadev, GOG 9929)
NRG-GY-TS034/CSC0244 (Mayadev, NRG-GY017)

IV. Ovarian Cancer Subcommittee

New Concepts

a. **RT2504**, A Phase II Trial of balstilimab and botensilimab for recurrent clear cell carcinoma of the ovary, fallopian tube or peritoneum (Cara Matthews)
b. **RT2507**, A Single Arm Phase II Evaluation of Gemcitabine, Cisplatin, Bevacizumab and Pembrolizumab for Recurrent or Persistent Ovarian Clear Cell Carcinoma (Ken Lin/John Farley)

Studies Under Development

a. **NRG-GY034**, A Randomized Phase 1/2 Trial Evaluating the Addition of ASTX660 (Tolinapant) to Weekly Paclitaxel with Or without Bevacizumab in Patients with Recurrent Platinum Resistant and Platinum Refractory Epithelial Ovarian Cancer (Kristen Zeligs)
b. **NRG-GY036**, A Phase III Trial of One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab, in Patients with BRCA1/2 Mutated Or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum-Based Chemotherapy (Ying Liu)
c. **RT2414**, GnRH (Elagolix) AnTagonism in recurrent granulosa cell tumor: a single-arm phase II trial (GREAT trial) (Adrieanne Mallen, Jose Conejo-Garcia)
d. **OV2431**, A Phase II trial of sacituzumab govitecan (SG) versus standard of care carboplatin and liposomal doxorubicin chemotherapy, both with or without physician's choice bevacizumab, in patients with platinum-sensitive ovarian cancer who have progressed on prior maintenance PARP inhibitor therapy (Rebecca Porter)

Active Studies:

a. **NRG-GY019**, A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low Grade Serous Carcinoma of the Ovary or Peritoneum (Amanda Nickles Fader)
b. **NRG-GY027**, Phase I/IB Safety and Pharmacodynamic Study of Neoadjuvant (NACT) Paclitaxel and Carboplatin with Ipatasertib as Initial Therapy of Ovarian Cancer PTMA 100805 (Katherine Fuh)

c. **NRG-GY031**, A Phase 1B Study of Combination ATR (M1774) and BET Inhibition (ZEN003694) to Exploit ARID1A Loss in Recurrent Ovarian and Endometrial Cancer (Fiona Simpkins)

d. **NRG-GY033**, A Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Combination with Leuprolide Acetate and Exemestane in Recurrent Adult-Type Ovarian Granulosa Cell Tumor (Elizabeth Hopp)

Closed Studies, primary manuscript NOT published (Ovarian): GY009, GY021, GY023
Closed Studies, primary manuscript NOT published (DT): GY014
Closed Studies, primary manuscript NOT published (Rare Tumor):
Closed Studies (primary manuscript published): 213, 262, GY003, GY004, GY005
Terminations:
Biospecimen Access:
NRG-GY-TS022 (Matei, GOG-0136-OV) Publication submitted to NRG Pubs
NRG-GY003-CSC0255 (Zamarin, NRG-GY003) Distribution in progress

V. Uterine Corpus Cancer Subcommitee

New Concepts

a. **UC2505**, Evaluating the safety and efficacy of lenvatinib/everolimus/letrozole in patients with advanced endometrial cancer who have progressed on immunotherapy (Jill Tseng/ Sami Dwabe)

b. **UC2508**, A Phase III Study Evaluating Endocrine Therapy compared to chemotherapy as adjuvant Therapy for patients with advanced stage NSMP Endometrial Cancer. (Bradly Corr/Britt Erickson/Ramez Eskander/Angeles Alvarez Secord)

c. **UC2509**, Neoadjuvant carboplatin/paclitaxel/dostarlimab followed by maintenance dostarlimab for advanced stage, MMRd endometrial cancer: Is there a role for interval debulking surgery? (Brenna Swift)

Studies Under Development

a. **NRG-GY035**, A Randomized Phase III Trial of Carboplatin, Paclitaxel, Pembrolizumab versus Carboplatin, Paclitaxel, Bevacizumab versus Carboplatin, Paclitaxel, Pembrolizumab, Bevacizumab in the Treatment of pMMR, TP53 Mutated Advanced or Recurrent Endometrial Cancer (Amanda Nickles Fader)

b. **UC2108**, Phase II Study of Androgen Receptor (AR) Inhibition by Darolutamide in Women with Advanced or Recurrent AR Positive ER Low Endometrial Cancer (Katherine Kurnit)

c. **UC2229**, Evaluating a Molecular based protocol for EaRly stage high-intermediate risk Endometrial carcinomas directed by ctDNA: The EMERGE-C Trial (Kuroki, Lee, Pothuri, Secord, Hacker)

d. **UC2417**, A Study of Dactinomycin and Pembrolizumab in Patients with "Hard-to-Cure" Low-Risk and High-Risk (Risk Score 7-12) Gestational Trophoblastic Neoplasia
e. **UC2418**, A Preoperative Window Study of Pembrolizumab with or without Radiation Therapy for Molecularly High Risk (MMRd, p53abn, NSMP high risk) Resectable Endometrial Cancer (Matthew Harkenrider)
f. **UC2419**, A Randomized Surgical Window Pilot Investigation of Endocrine Priming to Enhance Immune Response in Endometrial Cancer (Gloria Huang)
g. **UC2439**, A Phase III Trial of a weight loss intervention with Tirzepatide vs enhanced usual cared in overweight or obese patients with mismatched repair proficient Stage III Endometrial cancer (Angela Green/ V Bae Jump, V Makker)
h. **UC2440**, One year vs two years of immunotherapy in recurrent/metastatic dMMR endometrial cancer (Backes)
i. **UC2442**, Maintenance therapy for newly diagnosed stage III-IVA pMMR/p53wt endometrial cancer (Backes)

Active Studies:

a. **NRG-GY025**, A Randomized Phase II Trial of Nivolumab and Ipilimumab Compared to Nivolumab Monotherapy in Patients with Deficient Mismatch Repair System Recurrent Endometrial Carcinoma (Haider Mahdi)
b. **NRG-GY026**, A phase II/III study of paclitaxel/carboplatin alone or combined with either trastuzumab and hyaluronidase-oysk (HERCEPTIN HYLECTA) or pertuzumab, trastuzumab, and hyaluronidase-zzxf (PHESGO) in HER2 positive, stage I-IV endometrial serous carcinoma or carcinosarcoma (Britt Erickson)
c. **NRG-GY028** (PTMA#100828), A Phase IB and Randomized Phase II Trial Of Megestrol Acetate with or without Ipatasertib in Recurrent or Metastatic Endometrioid Endometrial Cancer (Michaela Onstad Grinsfelder)
d. **NRG-GY032**, A Phase II Study of Tailored Adjuvant Therapy in POLE-Mutated and p53-Wildtype/NSMP Early Stage Endometrial Cancer (Rainbo Blue & Taper)
   SUBSTUDY A: RAINBO POLEmut-BLUE: Refining Adjuvant treatment IN endometrial cancer Based On molecular features (RAINBO) TransPORTEC platform trials
   SUBSTUDY B: Tailored Adjuvant Therapy in p53-Wildtype/NSMP Early Stage Endometrial Cancer (TAPER)
   CCTG Protocol Number: EN.10 (CCTG Study Co-Chairs: Kathy Han, Jessica McAlpine)

Closed Studies, primary manuscript NOT published (Corpus): NRG-GY012 (Part 1 published), NRG-GY020
Closed Studies, primary manuscript NOT published (DT): 286B
Closed Studies (Primary manuscript published): 258, NRG-GY018

Biospecimen Access:
MP2PRT (Cosgrove, GOG-0210) Distribution/testing in progress
Nav1901/CSC0148 (Secord, GOG-0258) Testing in progress
Nav2461/CSC0162 (Secord, GOG-0249) Distribution/testing in progress; SGO 2025 abstract
Nav2801/CSC0177 (Bae-Jump, GOG-0286B) Manuscript in progress
NRG-GY-TS023/CSC0191 (Leslie, NRG-GY011) Distribution in progress
NRG-GY-TS024/CSC0191 (Yang, NRG-GY011) Distribution in progress
NRG-GY-TS029 (Madueke-Laveaux, GOG-0136-UC) Testing in progress
NRG-GY018-CSC0249 (Aghajanian, NRG-GY018) Distribution in progress

VI. **Developmental Therapeutics Committee**

Active Studies:

a. **NRG-GY022**, Assessment of carboplatin clearance predictors: a companion PK study to NCI sponsored clinical trials or standard of care treatments using carboplatin (Sarah Taylor, Jan Beumer)

b. **EAY191-N2**, Phase 2 Trial of Fulvestrant and Binimetinib in Patients with Hormone Receptor-Positive Metastatic Breast Cancer with a Frameshift or Nonsense Mutation or Genomic Deletion in NF1: A ComboMATCH Treatment Trial (Bora Lim)

c. **EAY191-N4**, A Randomized Trial of Selumetinib and Olaparib or Selumetinib Alone in Patients with Recurrent or Persistent RAS Pathway Mutant Ovarian and Endometrial Cancers: A ComboMATCH Treatment Trial (Shannon Westin)

d. **EA191-N5**, A randomized trial of neratinib, a pan-ERBB inhibitor, alone or in combination with palbociclib, a CDK4/6 inhibitor, in patients with HER2+ gynecologic cancers and other solid tumors (Haider Mahdi, MD, MPH)

VII. **Cancer Prevention and Control Committee Report**

NCORP Studies:

Active Studies:

a. **NRG-CC008**, A Non-Randomized Prospective Clinical Trial Comparing the Non-Inferiority of Salpingectomy to Salpingo-oophorectomy to Reduce the Risk of Ovarian Cancer Among BRCA1 Carriers (SOROC) (Kathryn Pennington, Warner Huh)

b. **NRG-CC010**, A Phase III Trial Of The Impact Of Sentinel Lymph Node Mapping On Patient Reported Lower Extremity Limb Dysfunction In Endometrial Cancer (Edward Tanner)

Closed Studies:

GOG-278, Evaluation of Physical Function and Quality of Life (QOL) Before and After Non-Radical Surgical Therapy (Extra Fascial Hysterectomy or Cone Biopsy with Pelvic Lymphadenectomy) for Stage IA1 (LVSI+) and IA2-IB1 (=/<2CM) Cervical Cancer

VIII.	**Patient Centered Outcomes Research (PCOR) Committee Report**	
IX.	**Translational Science Committee Report**	
X.	**Cancer Care Delivery Research Committee Report**	

Additional Notes:

Session Title	Head & Neck Cancer General Committee		
Date	Friday, January 17, 2025	**Chair**	Sue Yom, MD, PhD
Time	4:30 pm – 6:00 pm MT	**Vice Chairs**	Erich Sturgis, MD, MPH Stuart Wong, MD Neil Hayes, MD, MS, MPH

Meeting Agenda

Time	Topic	Presenter
	A. Head and Neck portfolio and membership update	Sue Yom, MD, PhD
	B. Active developing studies	
	• **NRG-HN013 concept** (SWOG leading): Randomized Phase II Study of Amivantamab vs. Cetuximab in Immunocompromised Participants with Recurrent Inoperable or Metastatic cSCC	Paul Swiecicki, MD
	• **NRG-HN015** (formerly HN2405 concept): Phase II Randomized Trial of Neoadjuvant Chemotherapy or Chemo-immunotherapy in Patients with Recurrent/Persistent PD-L1 Enriched SCCHN Undergoing Salvage Surgery	Nabil Saba, MD
	• **NRG-HN2437 concept:** Randomized Phase II Trial of Radiotherapy with Concurrent Cetuximab vs. Carboplatin and Paclitaxel in Patients with Stage III-IVB HNC with a Contraindication to Cisplatin	Loren Mell, MD
	• **NRG-HN2436 concept**: Randomized Phase III Trial for **D**e**IN**tensification of Radiation Therapy with **A**daptation to **M**easurement of **O**ropharyngeal Cancer Patients' **H**uman**P**apilloma**V**irus DNA (**DINAMO-HPV)**	Jillian Tsai, MD
	C. Review of active studies	
	• **RTOG 1216:** Phase III RT+cisplatin vs. RT+docetaxel+cetuximab vs. RT+cisplatin+atezolizumab for "high risk" resected HNSCC	Julie Bauman, Paul Harari, David Rosenthal
	• **NRG-HN006**: Phase II-III SLN Biopsy vs. END in T1-2N0 oral cavity cancer	Stephen Lai
	• **NRG-HN008**: Phase I RT + DNA-PK inhibitor in cisplatin-ineligible patients with high risk LA HNSCC	Maura Gillison, Michael Samuels
	• **NRG-HN009:** Phase II-IIIR RT with q3week cisplatin (100 mg/m^2 x 3) vs q1week cisplatin (40 mg/m^2 x 7) for locoregionally advanced HNSCC	Paul Harari

• **NRG-HN010:** Phase II HER2-targeted therapies in HER2-expressing recurrent/metastatic salivary duct/SGC	Alan Ho
• **NRG-HN011:** Phase II Nivolumab vs Nivolumab+**Re**latlimab as **Main**tenance after First-line Platinum-Gemcitabine-Nivolumab in EBV Recurrent/Metastatic NPC **(REMAIN)**	Brigette Ma
• **NRG-HN014:** Phase II Neoadjuvant Immunotherapy w/ Response-Adapted Treatment vs. SOC for Resectable cSCC	Neil Gross
• **RTOG 3507:** Phase II ReRT +/- Pembrolizumab in Locoregionally Recurrent HNSCC	Stuart Wong
• **RTOG 3521:** Single-Arm Study of **T**oripa**l**imab in Combi**n**ation w/ Ci**s**platin and Gemci**t**abine in **R**ecurrent **M**etastatic **N**asopharyngeal Carcinoma Systemic **T**reatment Naïve Participants **(TRANSPARENT)**	Anna Spreafico
D. Report on publications and protocols closed to active accrual	Sue Yom
E. NRG Championed Trials updates	Sue Yom
F. NCI Head and Neck Steering Committee update	Loren Mell

Additional Notes:

Session Title	NRG Oncology Health Disparities Committee		
Date	January 16, 2024	**Chair(s)**	Jennifer Wenzel, PhD, RN, CCM, FAAN
Time	10:15 am - 11:15 am MT	**Vice Chair(s)**	Evan Graboyes, MD, MPH, FACS

Meeting Agenda

Time	Topic	Presenter
10:15 am - 10:25 am	Welcome & Introductions	Jennifer Wenzel, PhD, RN, CCM, FAAN Evan Graboyes, MD, MPH, FACS
10:25 am – 10:40 am	Research Spotlight-- Health Equity in Genetic Testing for Patients with Solid Tumors	Stephanie Reider, MD, PhD
10:40 am – 10:50 am	Clinical Trial Enrollment Updates - Statistics/Metrics - SDMC Reports	Mylin Torres, MD / Reena Cecchini, PhD, MS
10:50 am – 11:10 am	Research Concept Development HDC Updates	Noël Arring, DNP, PhD, RN / Evan Graboyes, MD, MPH, FACS

Additional Notes:

11:30 am – 12:00 pm ***HDC Special Interest Group (SIG) Breakout Sessions***

(Please check the NRG meeting schedule for the SIG breakout rooms)

- HDC Research Concept Development
- HDC Rural
- HDC Older Adult
- HDC Research Implementation

Please join us for the first time for individual breakout sessions for each of the Health Disparities Special Interest Groups. The SIG Breakout Sessions are open to both HDC SIG members and those interested in finding out more about who we are and what we do. Each session will provide a brief overview of their function/purpose within NRG Oncology and the HDC and include time for your questions and recommendations. Find out what each SIG has been doing this past year, what our goals and plans are for 2025, and how you can be involved.

Session Title	HDC Special Interest Group (SIG) Breakout Sessions
Date	January 16, 2024
Time	11:30 am – 12:00 pm MT

Meeting Agenda

Time	Topic	Presenter
	Please join us for the first time for individual breakout sessions for each of the Health Disparities Special Interest Groups. The SIG Breakout Sessions are open to both HDC SIG members and those interested in finding out more about who we are and what we do. Each session will provide a brief overview of their function/purpose within NRG Oncology and the HDC and include time for your questions and recommendations. Find out what each SIG has been doing this past year, what our goals and plans are for 2025, and how you can be involved.	
11:30 am–12:00 pm	***Please join the HDC Special Interest Groups that most interest you.***	
	HDC Older Adult Special Interest Group Older adults experience a high burden of cancer but are often not represented in cancer research. The focus of the Older Adult Research SIG is to develop concepts that address issues that can improve care and the experience of older adults with cancer. The Older Adult SIG has developed therapeutic studies in older adults with breast and head and neck cancers, as well as trials looking at chemotherapy completion rates, pre-operative assessment, and post-operative outcomes in older women with gynecologic cancers	William Tew, MD
	HDC Research Concept Development Special Interest Group The Research Concept Development (RCD) SIG is the primary home for developing concepts and protocols that address disparities in cancer care outcomes among special populations. Populations of interest include but are not limited to racial and ethnic minoritized groups, older adults, people with cancer living in rural areas, sexual and gender identity minoritized patients, and other medically underserved groups. In so doing, the RCD provides support and mentorship for developing concepts and processing them through NCORP approval. In addition to providing a forum to discuss investigator-initiated concepts from HDC members, the RCD serves to enhance the pipeline of disparity-focused concepts by providing a platform for discussion of developing concepts from NCORP pilot projects and NRG Oncology/NCORP Health Equity fellows. Finally, the RCD works with NRG research committees and working groups to develop projects that leverage existing NRG Oncology and NCORP datasets to enhance health equity through ancillary data requests.	Evan Graboyes, MD, MPH, FACS / Noël Arring, DNP, PhD, RN

HDC Research Implementation Special Interest Group Barriers continue to hamper enrollment into cancer clinical trials of groups traditionally underrepresented including, but not limited to older adults, racial and ethnic minorities, rural populations, and the LGBTQIA+ community. This SIG will continue our work in underserved enrollment to NRG Oncology CTEP and NCORP trials. Activities include 1) assist investigators with protocol development to minimize enrollment barriers and address challenges to accrual of diverse populations in ongoing studies, 2) review trial accrual reports broken down by race, ethnicity, gender, and age to provide feedback and support to investigators as needed, 3) provide guidance to study teams developing protocols with a cancer health disparities endpoint 4) plan and host a yearly health disparities workshop at the NRG Oncology meeting, 5) support a diverse workforce by implementation of a mentorship program in NRG Oncology, and 6) provide additional educational activities to the NRG Oncology community to promote equity in cancer care	Victoria Bae-Jump, MD, PhD / Mylin Torres, MD
HDC Rural Special Interest Group Where a person lives matters to their health. Individuals living in rural areas experience unique and challenging obstacles related to cancer screening, treatment, and symptom support. The Rural Health SIG leverages the network of NRG NCORP sites that serve rural residents to determine research priorities. With these priorities, the SIG be focused on developing concepts targeted to improve the care and experience of individuals living in rural areas related to cancer. Opportunities to adapt evidence-based interventions in academic settings to testing in rural communities are also a priority.	Na Tosha Gatson, MD, PhD, FAAN / Shearwood McClelland, MD

Additional Notes:

Session Information

Session Title	NRG Oncology Imaging Committee		
Date	Jan 13,2025	Chair(s)	Daniel Pryma MD
Time	1:30PM-3:30PM EST	Vice Chair(s)	Amy Fowler MD, PhD
Room Location	Virtual Only		

Meeting Agenda

TIME Eastern Standard Time	Topic	Presenter
1:30–1:35pm	Greetings	Amy Fowler MD, PhD
1:35-1:50pm	Update NRG Theranostics Subcommittee	Thomas Ng MD, PhD
1:50-2:05pm	Disease site Updates since last meeting	
	▪ H&N	Cynthia Wu, MD
	▪ Brain	Virginia Hill, MD
	▪ Breast	Amy Fowler, MD, PhD
	▪ GYN	Karthik Sundaram, MD
	▪ GI	Aoife Kilcoyne, MD
	▪ GU	Ashesh Jani, MD Bill Hall, MD
	▪ Lung	Andrew Baschnagel, MD
2:05-2:10pm	Update from IROC PHL for NRG Trials	Jim Gimpel, RT (R) (MR)
2:10-2:32pm	Dose Summation	Yixiang Liao, PhD
2:32-2:55	Heart Substructures	Mihaela Rosu, PhD
2:55-3:30pm	NRG Imaging and Medical Physics Joint Symposium ***Challenges of cancer trials in the PSMA era***	Osama Mawlawi, PhD Ashesh Jani, MD Bill Hall, MD

Session Title	Immunotherapy Subcommittee		
Date	January 14, 2025	**Chair(s)**	Susanna Ulahannan, MD
Time	1-2 pm MT	**Vice Chair(s)**	Janice Lu, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Cancer immunotherapy with immune checkpoint inhibitors induces an immunoregulatory deficiency that explains both their benefits and harms.
2. Patients with myriad co-morbid conditions can benefit from cancer immunotherapy under certain conditions, but a proper risk-benefit analysis should be made in selecting therapeutic options.
3. Rechallenge with ICIs is an increasingly important question, but determining the need for rechallenge with ICIs and the nature of the irAEs for the individual patient scenario is critical for clinical decision-making.

Meeting Agenda

Time	Topic	Presenter
	Introductions	Susanna Ulahannan, MD
	CME Presentation	
	Learning from Our Mistakes: The Intersection of Cancer, Autoimmunity, and Immunology	Elad Sharon, MD
	NRG Concept Review	Susanna Ulahannan, MD

Additional Notes:

Session Title	International Members Subcommittee Meeting		
Date	Thursday, January 16th	**Chair(s)**	Ben Corn, MD and Keiichi Fujiwara, MD
Time	10:00 – 11:00 AM MT	**Vice Chair(s)**	Jess Marston and Kate Wiser

Meeting Agenda

Time	Topic	Presenter
10:00 – 10:10 AM	Welcome and Opening Remarks	Ben Corn, MD Keiichi Fujiwara, MD
10:10 – 10:15 AM	Audit Update	Mary Jo Antonelli
10:15 – 10:25 AM	International Membership News	Karan Boparai
10:25 – 10:40 AM	NRG-BN012 Study Spotlight	Stuart Burri, MD
10:40 – 10:45 AM	Open Protocols for International Participation	Kate Wiser
10:45 – 10:50 AM	International Site Reminders	Jess Marston
10:50 – 11:00 AM	Closing Remarks, Questions, and Discussion	Ben Corn, MD Keiichi Fujiwara, MD

Additional Notes:

Session Title	NRG Oncology General Lung Cancer		
Date	January 17, 2025	**Chair(s)**	Jeff Bradley
Time	4:30-6:15pm	**Vice Chair(s)**	Jessica Donington Marty Edelman

Meeting Agenda

Time	Topic	Presenter
4:30 - 4:40pm	NRG-LU007: Phase II/III ES-SCLC; chemo + atezolizumab +/- RT	Quynh-Nhu Nguyen
4:40-4:55pm	Brain Met trials in lung cancer; NRG CC009, NRG BN012, NRG BN013, and NRG BN 014	Rupesh Kotecha
4:55-5:05pm	NRG-LU008: Stage III using SBRT to primary; CRT to nodes	Chuck Simone
5:05-5:20pm	LungMAP update	Sajama Waqar
5:20-5:40pm	**Invited talk:** PFS as a surrogate endpoint for OS in lung cancer trials	Chen Hu
5:40-6:00pm	**Invited talk:** Concurrent CRT + IO does not improve outcomes in lung cancer; Review of data and next steps	Kristin Higgins

Additional Notes:

Session Title	Medical Oncology Committee		
Date	January 13, 2024	**Chair**	Corey Langer, MD
Time	0900-1100 MT	**Co-Chair**	Deborah Armstrong, MD
Program Facilitators			

Learning Objectives

Following this activity, participants will be better able to:

1. Understand disease-specific clinical trial outcomes and major advances from ASCO and ESMO, and other critical meetings and presentations
2. Identify unique studies involving systemic therapy in the Medical Oncology sphere
3. Itemize the accomplishments of the Pharmacy and Immunotherapy Subcommittees and their bearing on protocol conduct

Meeting Agenda

Time	Topic	Presenter
0900	Introductions	Corey Langer, MD
0905	Lung Disease Site Updates	Martin Edelman, MD
0950	ComboMatch Update	Roisin O'Cearbhaill, MD
1000	GU Disease Site Updates	Oliver Sartor, MD
1030	Pharmacy Subcommittee Update	Judith Smith, PharmD
1040	NCORP overview and Chair position opportunities	Lisa Kachnic, MD Erica Field MPH, MHA, CCRP
1050	Immunotherapy Subcommittee Update	Susanna Ulahannan, MD

NRG ONCOLOGY™

NRG Medical Physics Subcommittee Semiannual Meeting Agenda

CENTER FOR INNOVATION IN RADIATION ONCOLOGY (CIRO)

Session Information

Session Title	NRG Medical Physics Subcommittee Virtual Agenda		
Date	January 13, 2025	Chair(s)	Ying Xiao, PhD
Time	3:30 – 5:00pm ET 1:30 – 3:00pm MT	Vice Chair(s)	Stanley Benedict, PhD
Room Location	Virtual Only		
	2:55 pm – 3:30pm ET Virtual Only Joint Imaging and Medical Physics Symposium: *(1:00 pm – 1:30 pm MT)* ***Challenges of Cancer Trials in PSMA Era*** ***Presenters: Osama Mawlawi, PhD, Ashesh Jani, MD, Bill Hall, MD***		

Meeting Agenda

Eastern Times listed below	Topic	Presenter
3:30 – 3:32pm	Welcome, Introductions • Subcommittee Updates	Ying Xiao, PhD Stanley Benedict, PhD
3:32 – 3:40pm	NCI/NCTN Updates • NCI Communications • NCTN Medical Physics	Ceferino Obcemea, PhD
3:40 – 3:50pm	NRG QA Report • IROC Houston • IROC Philadelphia RT (Contouring & Dosimetry) • IROC Philadelphia Imaging (reporting at Imaging)	Stephen Kry, PhD Ying Xiao, PhD Mark Rosen, MD
3:50 – 4:15pm	Disease Site Reports • Brain • Breast • GI • GU • GYN • H&N • Lung • NCORP	Yunfeng Cui, PhD / Fang-Fang Yin, PhD Guang-Pei Chen. PhD / Jean Moran, PhD William Parker, PhD/ Gemma Davies, PhD Mihaela Rosu, PhD Hayeon Kim, PhD / Cecilia Lee, PhD Nataliya Kovalchuk, PhD / Ping Xia, PhD Martha Matuszak, PhD /Timothy Ritter, PhD Yimei Huang, PhD / Tian Liu, PhD

4:15 – 4:25pm	Modality Technology Reports • Notable Technologies (Proton) • Proton SBRT	 Xiaoying Liang. PhD Liyong Lin. PhD
4:25 – 4:55pm	Working Group and Other Updates • Recommendations & Guidelines for Clinical Trials Involving Artificial Intelligence Assisted Automated Segmentation in Radiotherapy • AI for Radiotherapy Treatment Planning • FLASH • SFRT • Radiomics Phantom *Please NOTE times below for these updates:* *Dose Summation (Presented during Imaging at 2:10 pm – 2:32 pm ET)* *Data Curation (~~Presented during Imaging at 2:25 pm – 2:40 pm ET)~~ Postponed* *Heart sub-structure (Presented on Imaging at 2:32 pm – 2:55 pm ET)*	 Sharon Qi. PhD / Yi Rong, PhD Xun Jia, PhD / Quan Chen, PhD Jennifer Zou, PhD Heng Li, PhD Jason Sohn, PhD *Yixiang Liao, PhD* *~~Yi Rong, PhD~~* *Mihaela Rosu, PhD*
4:55pm	Other Business: Questions/ General Discussions	
5:00pm	Adjournment	

Session Title	Neurosurgery Working Group Meeting Agenda		
Date	January 17, 2025	**Chair(s)**	Michael Vogelbaum MD, PhD
Time	10:15 – 11:45am AT	**Vice Chair(s)**	Mark Gilbert, MD; Minesh Mehta, MD; Arnab Chakravarti, MD; Mei Polley, PhD

Workshop Agenda

Time	Topic	Presenter
10:15 – 10:20am	**Opening Remarks**	Michael Vogelbaum MD, PhD
10:20 – 10:45am	NRG-BN2501	Raleigh
10:45 – 11:05am	Concept: SRS vs. fSRS for VS	Wang
11:05 – 11:30am	Concept: Pre-op SRS vs. fSRS for brain met	Prabhu
11:30 – 11:45am	**Other Business / Closing**	

Session Title	Ovarian Subcommittee Workshop		
Date	January 17, 2025	**Chair(s)**	Kathleen Moore, MD, MS
Time	1:00-3:00pm MT	**Vice Chair(s)**	Joyce Liu, MD, MPH; Rebecca Arend, MD (translational); Maggie Mullen, MD MSCI (translational, vice chair)
Program Facilitators			

Learning Objectives

Following this activity, participants will be better able to:

1. Review the status of completed and ongoing NRG/GOG clinical trials on the treatment of ovarian cancer
2. Review the status of approved NRG/GOG concepts that are under development
3. Apply standard and review procedures required to design, submit, and conduct a research protocol within NRG, including ancillary data proposals
4. Assure strict quality control of NRG/GOG clinical trials

Meeting Agenda

Note: The actual order and timing of topics and discussion is subject to change, depending on availability of participants

Time	Topic	Presenter
1:00-1:05 pm	Introduction • Review of learning objectives • Statements regarding potential conflicts of interests • Committee Member Rotations	Kathleen Moore, MD, MS
1:05-1:35 pm	Invited Presentation: Ovarian Cancer Funding Opportunities, Congressionally Directed Medical Research Programs (CDMRP)	Sagar Ghosh, PhD, MBA
1:35-1:50 pm	Clinical Trial Preview: NRG-GY036	Ying Liu, MD, MPH
1:50-1:55 pm	Review of Closed Studies (not terminated)	Kathleen Moore, MD, MS
1:55-2:15 pm	Review of Active Studies	Kathleen Moore, MD, MS
	• **NRG GY021**: Translational update	
	• **NRG CC008**: Brief update and eligibility reminders	
2:15-2:30 pm	Review of Approved Concepts Under Development	Kathleen Moore, MD, MS
2:30-3:00 pm	Review of New Concepts and a Discussion on Clear Cell Ovarian Cancers	Moderated by Chair and Vice Chairs

- **RT2504**: A Phase II trial of balstilimab and botensilimab for recurrent clear cell carcinoma of the ovary, fallopian tube or peritoneum (Cara Mathews)
- **RT2507**: A Single Arm Phase II Evaluation of Gemcitabine, Cisplatin, Bevacizumab and Pembrolizumab for Recurrent or Persistent Ovarian Clear Cell Carcinoma. (Ken Lin/John Farley)

Additional Notes:

List of Closed Studies (not terminated) – status updates since Jul 2024 meeting are in blue.

Study	Title	Notes
GOG-0213	A phase III randomized controlled clinical trial of carboplatin and paclitaxel (or gemcitabine) alone or in combination with bevacizumab followed by bevacizumab and secondary cytoreductive surgery in platinum-sensitive, recurrent ovarian peritoneal primary and fallopian tube cancer (Robert Coleman)	Lancet Oncol 2017 NEJM 2019
GOG-0262	A randomized phase III trial of every-3-weeks paclitaxel versus dose dense weekly paclitaxel in combination with carboplatin with or without concurrent and consolidation bevacizumab in the treatment of primary stage III or IV epithelial ovarian, peritoneal or fallopian tube cancer (John K Chan)	NEJM 2016
GOG-0273	Chemotherapy toxicity in elderly women with ovarian, primary peritoneal, or fallopian tube cancer (Vivian E von Gruenigen)	Modified dose dense cohort manuscript in draft form
NRG-GY003	Phase II Randomized Trial of Nivolumab with or without Ipilimumab in Patients with Persistent or Recurrent Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Cancer (Zamarin)	J Clin Oncol 2020
GOG-0281	RP2/3 study to assess efficacy of Trametinib in recurrent or progressive low grade serous ovarian or peritoneal cancer. (David Gershenson)	Presented IGCS 2019 Lancet 2022
GOG-0264	RP2 trial paclitaxel-carboplatin vs BEP for newly diagnosed advanced-stage and recurrent chemo-naïve sex cord stromal tumors of the ovary (Jubilee Brown)	Presented IGCS 2020 Gyn Oncol 2024
NRG-GY004	Phase III Study Comparing Single-Agent Olaparib or the Combination of Cediranib and Olaparib to Standard Platinum-Based Chemotherapy in Women with Recurrent Platinum-Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Joyce Liu and Ursula Matulonis)	Presented ASCO 2020 J Clin Oncol 2022 OS data presented at ESMO 2023
NRG-GY005	A Randomized Phase II/III Study of the Combination of Cediranib and Olaparib Compared to Cediranib or Olaparib Alone, or Standard of Care Chemotherapy in Women with Recurrent Platinum-Resistant or -Refractory Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (Jung-Min Lee and Angeles Alvarez Secord)	Closed to accrual 10/02/2020 Total accrual 562 J Clin Oncol 2024
NRG-GY009	A Randomized, Phase II/III Study of Pegylated Liposomal Doxorubicin and Atezolizumab *vs* Pegylated Liposomal Doxorubicin/Bevacizumab and Atezolizumab *vs* Pegylated Liposomal Doxorubicin/Bevacizumab in Platinum Resistant Ovarian Cancer (Roisin O'Cearbhaill, Carol Aghajanian)	Presented IGCS 2023
NRG-GY014 (DT1718)	A Phase II study of tazemetostat (EPZ-64438), an EZH2 inhibitor, in select gynecologic cancers (NCI CRDL LOI request). Limited sample size (n = 31), but requires genomics screening. (Ramez Eskander and David Hyman)	Closed to accrual 06/15/2022 Total accrual 62 Presented SGO 2024
NRG-GY023	A randomized phase II trial of triplet therapy (a PD-L1 inhibitor durvalumab in combination with olaparib and cediranib) vs. doublet therapy (olaparib and cediranib) vs doublet therapy (durvalumab and cediranib) vs physician choice chemotherapy in women with platinum-resistant recurrent epithelial ovarian cancer, primary peritoneal or fallopian cancer who have received prior bevacizumab (Jung-min Lee)	Presented ESMO 2023 Submitted CCR

NRG ONCOLOGY™

Winter 2025 – Phoenix, AZ
Semiannual Meeting Agenda

List of Active Studies (all metrics are as of 12/2024) – status updates since Jan 2024 meeting are in blue.

Study	Title	Notes
NRG-GY019 (RT1753)	A Phase III Randomized Three Arm trial of paclitaxel/carboplatin compared to paclitaxel/carboplatin/maintenance letrozole versus letrozole monotherapy in patients with stage II-IV primary low-grade serous carcinoma of the ovary or peritoneum. (Amanda Nickles-Fader)	Activated 8/26/19 418/457
NRG-GY021	Randomized Phase II Trial of olaparib + tremelimumab *vs* olaparib in platinum sensitive recurrent ovarian cancer/HRD+ and HRD. (Sarah Adams)	Closed to accrual 10/19/2020
NRG-GY022 (DT1833)	Assessment of carboplatin clearance predictors: PK protocol to allow for extra sample collection and collection of demographic data, laboratory values, and outcome data. (Liz Villaruz/Jan Beumer)	Activated 11/2019 289/350 Now enrolling male pts only
NRG-CC008 (CC1923) (NC1427) (CPC1206)	A non-randomized prospective clinical trial comparing the non-inferiority of salpingectomy to salpingo-oophorectomy to reduce the risk of ovarian cancer among BRCA1 carriers (SOROCk) (Walker/Huh/Pennington)	Activated 6/2020 697/2262 **Allows surgery by non-NCTN/NCORP surgeons**
AGCT1531 (RT1205)	Active Surveillance, Bleomycin, Carboplatin, Etoposide, or Cisplatin in Treating Pediatric and Adult Patients With Germ Cell Tumors (MaGIC, COG primary, AI Covens NRG)	Activated 5/2017 1041/2059
NRG-GY027	A Phase IB Trial of Ipatasertib plus paclitaxel and carboplatin in women undergoing neoadjuvant chemotherapy for treatment naïve, epithelial ovarian cancer (Katherine Fuh/Kathleen Moore)	Activated 6/27/2022 25/24 At full enrollment, waiting for DLT results
NRG-GY031 (DT2106)	A Phase IB study of combination BET protein inhibition (ZEN3694) and ATR kinase (M1774) for the treatment of recurrent ARID1A mutated clear cell and endometrioid ovarian carcinomas (Yasuto Kinose/Fiona Simpkins)	RSC 07/2021 LOI approved 6/21/22 Activated 08/31/23 13/57 New dosing amendment in development
NRG-GY033 (RT2141)	Phase II study of androgen receptor (AR) inhibition by darolutamide in combination with leuprolide acetate and exemestane in recurrent AR positive adult-type ovarian granulosa cell tumor (Elizabeth Hopp/Janet Rader)	RSC 05/2022 LOI approved 1/10/24 Activated 01/22/24 17/37 On hold for interim analysis

List of Approved Concepts Under Development – status updates since Jul 2024 meeting are in blue.

Concept	Title	Notes
NRG-GY034 OV2206	Randomized Phase 1/2 trial evaluating the addition of tolinapant to weekly paclitaxel with or without bevacizumab in patients with recurrent epithelial ovarian cancer (Zeligs/Annunziata)	OTF 05/2022 Revision to tolinapant reviewed at OTF 07/2022 RSC 10/2022 GCSC 11/16/2022 CTEP approval 03/27/23. Amendment for DDI cohort under development
NRG-GY036 OV2307	One vs. Two Years of Maintenance Olaparib, with or without Bevacizumab, in Patients with BRCA1/2 Mutated or Homologous Recombination Deficient (HRD+) Ovarian Cancer Following Response to First Line Platinum Based Chemotherapy (Ying Liu/Aghajanian)	OTF 03/17/23 RSC 05/10/23 CTEP approval 11/01/23. Pre-

Concept	Title	Notes
		activation amendment under review.
OV2431	Phase II trial of sacituzumab govitecan (SG) versus standard of care carboplatin and liposomal doxorubicin chemotherapy, both with or without physician's choice bevacizumab, in patients with platinum-sensitive ovarian cancer who have progressed on prior maintenance PARP inhibitor therapy (Porter/Liu/Moore/Corr)	OTF 11/15/24 RSC 01/22/25

Session Information

Session Title	Particle Therapy Working Group		
Date	Jan 17, 2025	Chair(s)	Charles B. Simone II, MD
Time	10:15 – 11:45am	Vice Chair(s)	N/A
Room Location	In person only		

Meeting Agenda

Time (AM)	Topic	Presenter
10:15 – 10:25	Welcome Address and Chair Update	Charles Simone II, MD
10:25 – 10:35	Update from NCI	Jeff Buchsbaum, MD
10:35 – 10:45	Update on Proton Center Credentialing by IROC	Paige Taylor, PhD
10:45 – 10:55	Update on Medical Physics Proton	Ying Xiao, PhD
10:55 – 11:05	GU Studies: GU008, GU009, GU010, GU013	Xinglei Shen, MD
11:05 – 11:15	Brain Studies: BN003, BN014	Minesh Mehta, MD
11:15 – 11:20	Lung Studies: LU008	Charles Simone II, MD
11:20 – 11:30	H&N Studies: • HN009, HN014 • CC013	Charles Simone II, MD Christina Chapman, MD
11:30 – 11:40	• GI Studies: GI003, GI006 • GI012 (in dev)	Ted Hong, MD Jennifer Wo, MD
11:40 – 11:45	• Open Discussion	All

Session Title	Patient-Centered Outcomes Research (PCOR) Committee Agenda		
Date	January 16, 2025	**Chair(s)**	Ben Movsas, MD
Time	3:30-5:00 pm	**Vice Chair(s)**	Ron Chen, MD

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss lessons learned from DCP rejections for Patient-Reported Outcomes (PROs) on trials to improve future trials with PROs.
2. Discuss improvement in QOL compliance and identify the next steps to further continued improvement.
3. Analyze appropriate PRO endpoints and instruments for use in NCTN Phase II and III clinical trials.

Meeting Agenda

Time	Topic	Presenter
3:30-3:35 pm	Welcome and Session Introduction	Ben Movsas, MD
3:35-4:00 pm	How to Enhance PRO Writeups/Designs	Ron Chen, MD
4:00-4:25 pm	PRO and QOL Data Compliance Update	Marcie Ritter, PhD Kandie Dempsey, DBA, MS, RN, OCN
4:25-4:50 pm	Liaison Updates and Developing Concepts	Ben Movsas, MD Ron Chen, MD
4:50-5:00 pm	Closing Remarks	Ben Movsas, MD Ron Chen, MD

Session Title	Pharmacy Subcommittee		
Date	January 14, 2025	**Chair**	Judith A. Smith, BS, PharmD, BCOP, CPHQ
Time	9:00 – 10:30am MT		

Learning Objectives

Following this activity, participants will be better able to:

1. Compare and contrast the emerging immunotherapies in clinical trials for HPV related cancers.
2. Discuss the supportive care resources available to investigators for management of common toxicities associated with chemotherapy.
3. Recognize the benefits of pharmacy review on NRG Oncology research protocols.

Meeting Agenda

Time	Topic	Presenter
0900	Introductions	Judith Smith, PharmD
0905	Highlights on Emerging Immunotherapies in Clinical Trials for the treatment of HPV Cancers.	Judith Smith, PharmD
0935	NRG Disease Site Committee Pharmacy Liaison Update	Judith Smith, PharmD
0945	Update from LPO Pharmacy Leadership Collaboration	Robin Lockhorst, Pharm.D
0950	Practice Recommendation Documents	Judith Smith, PharmD
	a. Final review of topics:	
	i. Skin toxicities	Robin Lockhorst, Pharm.D
	ii. Hyperphosphatemia	Anita Lammer, Pharm.D.
	iii. Hypothyroidism/Hyperthyroidism	David DeRemer, Pharm.D.
	b. Suggestions for new topics?	
1005	PMB Update	Kayla Dye, PharmD
1015	NRG Oncology Update	Judith Smith, PharmD
	a. Grant Resubmission	
	b. Annual call for NRG committee membership	
	i. Recruitment/ Disease site coverage ii. Guest attendees	
1025	Discussion/Other items	

Session Information

Session Title	NRG Radiation Oncology Committee		
Date	Jan 17,2024	Chair(s)	Evan Wuthrick, MD
Time	8:00 – 10:00 AM	Vice Chair(s)	Charles B. Simone II, MD Diandra Ayala-Peacock, MD
Room Location	(In-Person Only)		

Meeting Agenda

Time (AM)	Topic	Presenter
8:00 – 8:05 am	Welcome	Evan Wuthrick, MD
8:05- 8:40 am	Symposium: The State of Adaptive RT: Current Technology and Upcoming Clinical Trials	Hyun Kim, MD Adam Yock, PhD
8:40 – 8:45 am	NCI/NCTCN Updates • NCI Communications • NCTN Medical Physics	Jacek Capala, PhD
8:45 – 8:50 am	NRG RO Medical Physics Subcommittee	Ying Xiao, PhD
8:50 – 8:55 am	Theranostics Subcommittee	Jeff Michalski, MD
8:55 – 9:00 am	NRG RO Particle Therapy Working Group	Charles Simone II, MD
9:00- 9:05 am	GYN RO Working Group	Matthew Harkenrider, MD
9:05 – 9:10am	NRG Imaging Committee - Dan Pryma	Dan Pryma, MD
9:10 –9:25 am	Imaging and Radiation Oncology Core Group • IROC Houston • IROC Philadelphia • IROC Contouring and Dosimetry	Stephen Kry, PhD Densie Manfredi, BS Ying Xiao, PhD
9:25–9:55 am	Disease Site Reports – Updates on concepts near development a. H&N - Jimmy Caudell /Jason Chan b. Brain- Christina Tsien / Tony Wang c. Breast -Steven Chmura/Jose Bazan d. GYN- Eric Donnelly / Mark Bernard e. GI – William Hall / Kimberly Mak f. GU - Dan Krauss / Hiram Gay g. Lung - Stephen Chun MD /Pamela Samson h. Sarcoma - Philip Wong, MD / Dian Wang, MD	Jimmy Caudell, MD Christina Tsien, MD Jose Bazan, MD Eric Donnelly, MD William Hall, MD Hiram Gay, MD Stephen Chun, MD Philip Wong, MD

9:55- 10:00am	Questions	All

Session Information

Session Title	NRG Oncology Radiation Oncology GYN Working Group		
Date	January 16, 2025 Mountain Time In Person Only	Chair(s)	Matthew Harkenrider, MD
Time	5:30 PM - 6:30 PM	Vice Chair(s)	Diandra Ayala-Peacock, MD
Room Location	Phoenix Convention Center / West 105BC / 1st Level		

Meeting Agenda

Time	Topic	Presenter
5:30–5:32	A. Introductions / Announcements	Matthew Harkenrider, MD/ Diandra Ayala-Peacock, MD
5:32-5:40	B. Future Meeting Schedule • Zoom meeting prior to the NRG GYN meetings (if needed) for new GYN RT concepts, date TBD (1-2 weeks prior) • January 16-18, 2025 Phoenix Convention Center Phoenix, AZ • July 24-26, 2025 Marriott Marquis DC Washington, DC • January 22-24, 2025 Hilton San Francisco Union Square San Francisco, CA NRG Working Groups moving to Virtual only meetings from In Person	Matthew Harkenrider, MD Diandra Ayala-Peacock, MD
5:40-5:55	C. Educational Session: Role of predictive biomarkers in GYN cancers	Ann Klopp, MD
5:55-6:05	D. Radiopharmaceuticals for GYN cancers	Denise Fabian, MD

6:05-6:15	E. Discussion of New Concepts *"PI3Rad: Targeted Therapy with PI3K Inhibitor and Concurrent Radiation"*	Onyi Balogun, MD
6:15-6:25	F. Discussion of Previously Presented Concepts • CV2332 (Henson): Phase II non-inferiority trial of hypo fractionated RT with cisplatin for Cervical cancer • CV2346 (Glaser) CRT +/- IO for Vulva Concept • UC2418 (Harkenrider) PreOp Window of Pembro +/- RT for Molecularly High Risk Operable Endometrial Cancer	Christina Henson, MD Scott Glaser, MD Matthew Harkenrider, MD
6:25-6:30	G. Subcommittee Membership Needs H. Concluding Remarks and Wrap-Up QUESTIONS / DISCUSSION	Matthew Harkenrider, MD/ Diandra Ayala-Peacock, MD

Radiation Oncology Theranostics Subcommitte Semiannual Meeting Agenda

Session Information

Session Title	NRG Radiation Oncology Theranostics Subcommittee (TSC)		
Date	January 16, 2025	Chair	Jeff Michalski, MD
Time	3:00PM - 4:00PM Mountain Time	Vice-Chairs	Thomas Ng, MD / Oliver Sartor, MD
Room Location	In person only / Phoenix Convention Center		

Meeting Agenda

Time	Topic	Presenter
3:00–3:10	Welcome / Introductions	Jeff Michalski, MD/ Thomas Ng, MD/ Oliver Sartor, MD
3:10-3:55	1. Institutional technology survey/assessment a. AU experience (RO, NM, DR) b. RLT/RPT experience c. Dosimetry experience 2. Industry relationships 3. Concept generation/Protocol Development a. Brainstorm/data gathering of potential study topics	All
	4. NCI Update	Jacek Capala, PhD
	5. Theranostics Dosimetry / QA	Ying Xiao, PhD
	6. Imaging - NM/DR / IROC	Dan Pryma, MD/Michael Knopp, MD, PhD
	7. Medical Oncology	Oliver Sartor, MD
	8. <u>Disease Sites Liaisons</u> a. GU b. GI	Angela Jia, MD Kathryn Hitchcock, MD/Hyun Kim, MD
	c. Brain	Erik Sulman, MD/ Dan Cahill, MD
	d. Lung	Marty Edelman, MD

	e. H & N	Ana Kiess,MD / Hyu Kang, MD
	f. Breast g. GYN	Steve Chmura, MD Jyoti Mayadev, MD/Paul DiSilvestro, MD
	9. Future Meeting Schedule • Hold 2 Zoom meetings between Winter and Summer NRG Oncology IN PERSON meetings. (April 10th and October 9th -2nd Thursday) • July 24-26, 2025 Marriott Marquis DC Washington, DC • January 22-24, 2026 Hilton San Francisco Union Square San Francisco, CA	
3:55-4:00	Concluding Remarks and Wrap-Up QUESTIONS / DISCUSSION	Jeff Michalski, MD/ Thomas NG, MD/ Oliver Sartor, MD

SARCOMA WORKING GROUP AGENDA

Dian Wang, MD, PhD, Chair
Friday, January 17, 2025
10:00 AM – 12:00 PM

Active Studies

Phase I/II Trial of Preoperative Intensity Modulated Radiation Therapy (IMRT) for Retroperitoneal Sarcoma Using a Simultaneous Integrated Boost
(DeLaney/Yen-Lin Chen) Updated by Dr. Yenlin Chen

Registry to Evaluate the Safety and Feasibility of Treating Retroperitoneal Sarcomas with Permanently Implantable LDR CivaSheet
(Howell/Wang) *On Hold*

New Concepts

Phase IIR of SBRT and Pembrolizumab in Patients with Oligometastatic STS
(Phil Wong et al)

Hypofractionated Alternative Radiation with MOdulation of Neoadjuvant/peri-operative immunotherapY in Sarcoma (HARMONY)
(Phil Wong, CCTG trial)

Phase I of Dose-Escalating Trial in Treating High Grade Large STS
(Dian Wang)

Phase II Study of Neoadjuvant Chemoradiation Plus Immunotherapy for Angiosarcoma
(Parul Barry and Brian Van Tine)

Phase I Study on SBRT and Anlotinib in Relapsed/Refractory NRSTS
(Susan Hiniker PI (COG) and Phil Wong Co-PI (NRG) On Hold

A Randomized Phase II Trial of Doxorubicin + Pembrolizumab versus Doxorubicin Alone for the Treatment of Undifferentiated Pleomorphic Sarcoma (UPS) and Related Poorly Differentiated Sarcomas
(Seth Pollack, ECOG-ACRIN PI, and Brian Van Tine (NRG Champion) On Hold

Developing Concepts

Phase II study on Bacterial Decolonization for Preoperative Radiotherapy for Soft Tissue Sarcoma of the Lower Extremity
(Adam Olson) On Hold for Funding Support

AEWS2231: Randomized Phase III Trial of Vincristine-Irinotecan-Regorafenib in Combination with Vincristine-Doxorubicin-Cyclophoshamide in Patients with Newly Diagnosed Metastatic Ewing Sarcoma
(COG PI: Bhuvana Setty) under the review by CTEP (PI: Bhuvana Setty, approved by CTEP and under protocol development) Updated by Dian Wang

Phase II/III trial randomized study testing non-inferiority of shorter-course radiation versus standard fractionation for high-risk resectable extremity sarcoma
(S2310, PI: Jeremy Harris) *Under CTEP Review; On Hold*

Phase II Trial of Grid Sarcoma
(JW Snider ~ Majid Mohiuddin ~ Rob Griffin) On Hold

Phase II Checkpoint Inhibitor with Low Dose and High Dose RT (RadScopal) Trial of Soft Tissue Sarcoma Pulmonary Metastases
(Phil Wong) On Hold

Phase Ib Trial of Preoperative Zr-Bev Immuno-PET Guided Simultaneous Integrated Boost Radiation Therapy for Locally Advanced Non-Metastatic Soft Tissue Sarcoma of Extremity and Bodywall
(Wolfson) On Hold

AOST1921 (COG study concept): Pembrolizumab in Combination with Stereotactic Body Radiation Therapy (SBRT) and Surgery in Patients with Pulmonary Recurrence of Osteosarcoma
(Thomas Cash) *On Hold*

Phase II Trial to Investigate the Role of Peri-Operative RT in Desmoid Tumors Harboring CTNNB1 S45 Mutation
(Pollock/Welliver) *On Hold*

AOST2032: A Feasibility and Randomized Phase 2/3 Study of Cabozantinib in Combination with Cytotoxic Chemotherapy for Newly Diagnosed Osteosarcoma
(Bishop ~ NRG Champion Meena Bedi) *Under CTEP Review; On Hold*

Short Course vs Long Course Radiation for Resectable, High-Grade Soft-Tissue Sarcoma of the Extremity
(SWOG ~ Dr. Harris) On Hold

Phase 1b Study on of PARP Inhibitor and Radiation on Soft Tissue Sarcoma
(Welliver) *On Hold*

New Business

Session Title	Translational Science Brain Tumor Working Group		
Date	January 6th, 2025	**Chair(s)**	Arnab Chakravarti, MD
Time	1:00 – 2:30 pm MT	**Vice Chair(s)**	

Meeting Agenda

Time	Topic	Presenter
1:00 – 1:05 pm MT	Welcome and Introduction	Arnab Chakravarti, MD (Ohio State University)
1:05 – 1:25 pm MT	Updates from the University Medical Center (Utrecht)	P.A.J.T. (Pierre) Robe, prof dr. (University Medical Center Utrecht, The NMTherlands)
1:25 – 1:45 pm MT	Beyond the Bounds of Microhomology: Double-Strand Break Repair Utilizes Imperfect Sequence Matching	Sophie Webster, BA / Simona Dalin, PhD (The Broad Institute)
1:45 – 2:05 pm MT	AI-powered Tissue Segmentation for Quantitative Assessment of Response in Glioblastoma	George Ayoub, MD (Brigham and Women's Hospital)
2:05 – 2:25 pm MT	Updates to Image Guided Radiation Therapy	Joshua Palmer, MD (Ohio State University)
2:25 – 2:30 pm MT	Concluding Remarks	Arnab Chakravarti, MD (Ohio State University)

Additional Notes:

Session Title	Translational Science Genitourinary Cancer Working Group		
Date	January 7th, 2024	**Chair(s)**	Phuoc Tran, MD, PhD
Time	1:00 – 2:30 pm MT	**Vice Chair(s)**	

Meeting Agenda

Time	Topic	Presenter
1:00 - 105 pm MT	Welcome & Introductions	Phuoc Tran, MD, PhD (University of Maryland)
1:05 – 1:30 pm MT	Germline Influence on Prostate Cancer Metastasis and Treatment Response	Rana McKay, MD (University of California, San Diego
1:30 – 1:55 pm MT	Evolving Role of ctDNA in Genitourinary Cancers	Adam C. ElNaggar, MD (Natera, Inc.)
1:55 – 2:20 pm MT	Metabolic Dysfunction and Time-restricted Eating in Men with Prostate Cancer to Improve Radiotherapy Outcomes: Evidence, Challenges, and Translation	Yun Rose Li, MD, PhD (City of Hope)
2:20 – 2:30 pm MT	Closing Remarks	Phuoc Tran, MD, PhD

Additional Notes:

Session Title	Translational Science GYN		
Date	Fri, Jan 17, 2025	**Chair(s)**	Michael Birrer, MD, PhD
Time	4:30 pm – 6:00 pm	**Vice Chair(s)**	Heather Lankes, PhD, MPH

Learning Objectives

Following this activity, participants will be better able to:

1. Understand GYN translational science conducted by NRG and discuss GYN translational science projects.
2. Understand the organization and operations of the NRG Biospecimen Bank and the NRG Biospecimen Access process.
3. Assure strict quality control of NRG clinical trials, including GYN translational science.

Meeting Agenda

Time	Topic	Presenter
4:30-4:35	Opening remarks	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH
4:35-4:50	Uterine Corpus Subcommittee	Vickie Bae-Jump, MD, PhD Katherine Fuh, MD, PhD
4:50-5:05	Cervix/Vulva Subcommittee	Dmitriy Zamarin, MD, PhD
5:05-5:15	Ovarian Subcommittee	Rebecca Arend, MD Maggie Mullen, MD, MSCI Elizabeth Swisher, MD
5:15-5:20	Rare Tumor Subcommittee	Gloria Huang, MD
5:20-5:35	Developmental Therapeutics	Panagiotis Konstantinopoulos, MD, PhD
5:35-5:45	Genomic and molecular characterization of biomarkers associated with self-reported race/ethnicity in high-risk endometrial cancers from NRG Oncology/GOG Protocol 210, Molecular Staging of Endometrial Cancer	Casey Cosgrove, MD
5:45-5:55	Genomic and molecular characterization of biomarkers associated with tumor angiogenesis, DNA repair, and immunologic tolerance among exceptional responders and long-term survivors in NRG Oncology/Gynecologic Oncology Group protocol 240	Krish Tewari, MD

5:55-6:00	Closing remarks	Michael Birrer, MD, PhD Heather Lankes, PhD, MPH

Additional Notes:

Session Title	Translational Science Lung Cancer Working Group		
Date:	January 10th, 2025	**Chair**	Bo Lu, MD
Time	8:00 – 10:00 am MT	**Vice Chair(s)**	
Program Facilitators			

Meeting Agenda

Time	Topic	Presenter
8:00 – 8:05 am MT	Introduction and Welcome	Bo Lu, MD (University of Missouri)
8:00 – 8:25 am MT	Radiation Induced Cardiac Toxicity – Getting to the Heart of the Matter	Carmen Bergom, MD, PhD (Washington University at St. Louis)
8:25 – 8:45 am MT	Adapting Radiotherapy to Immunotherapy of Lung Cancer	Silvia C. Formenti, MD (Weill Cornell Medicine)
8:45 – 9:05 am MT	Evaluating Disparities Between Biospecimen Collection Versus Overall Trial Participants on NRG studies	Sophia Kamran, MD (Massachusetts General Hospital)
9:05 – 9:25 am MT	The SomaScan Assay: From Aptamers to Actionable Insights	Scott Keigan, MS/Jessica Kuzma, PhD (Standard BioTools)
9:25 – 9:45 am MT	Identifying the Optimal Treatment Strategies for Locally Advanced EGFRm NSCLC Patients	Fiona Hegi-Johnson, PhD (Peter MacCallum Cancer Center)
9:45 – 10:00 am MT	Concluding Remarks	Bo Lu, MD (University of Missouri)

Additional Notes:

Uterine Corpus Cancer Subcommittee Semiannual Meeting Agenda

Session Title	Uterine Corpus Cancer Subcommittee		
Date	Jan 17, 2025	Chair(s)	Matthew Powell, MD; Ann Klopp, MD
Time	10:00am-12:00pm	Vice Chair(s)	Katherine Fuh,MD, PhD; Victoria Bae-Jump MD, PhD
Room Location			

Session Information

Learning Objectives

Following this activity, participants will be better able to:

1. Discuss national and international priorities, goals and initiatives in the management of Uterine cancer.
2. Discuss currently active and developing NRG clinical trials on the prevention, diagnosis, and treatment of uterine corpus cancers.
3. Discuss promising therapeutics in development and potential translational research objectives and strategies for future clinical trials.
4. Apply standards and procedures needed to design, submit, (revise), and conduct a research protocol within the NRG
5. Outline both potential barriers and potential solutions to improve enrollment to NRG clinical trials in uterine corpus cancers to include international collaboration

Meeting Agenda

Time	Topic	Presenter
10:00–10:10	Topic Title (Welcome, Introductions)	Powell & Klopp
10:10-10:35	Route 66 Endometrial SPORE update	David Mutch
10:20-10:40	Further development of immunotherapy in Trophoblastic disease	N. Horowitz, Lua Eiriksson
10:40-10:55	1. **UC2508** A Phase III Study Evaluating Endocrine Therapy compared to chemotherapy as adjuvant Therapy for patients with advanced stage NSMP Endometrial Cancer. (Bradly Corr/Britt Erickson/Ramez Eskander/Angeles Alvarez Secord) **UC, TS, GYN**	Discussants:BJ Rimel, K. Fuh, B. Pothuri

	2. **UC2509** Neoadjuvant carboplatin/paclitaxel/dostarlimab followed by maintenance dostarlimab for advanced stage, MMRd endometrial cancer: Is there a role for interval debulking surgery? (Brenna Swift) **UC, GYN** 3. **UC2505 Evaluating the safety and efficacy of lenvatinib/everolimus/letrozole in patients with advanced endometrial cancer who have progressed on immunotherapy (Jill Tseng/ Sami Dwabe) UC, DT, GYN** 4. **Randomized Phase II Trial of Weekly Paclitaxel With and Without Inavolisib in Recurrent Endometrial Cancer**	Discussants:Namita Khanna, Emma Barber, Lisa Landrum Discussants: J. Barlin, L Duska, A. Secord Discussants: V Bae-Jump, K Fuh, B Slomovitz
10:55-11:15	Review of open and recently closed trials	H MacKay, R Eskander, F. Backes, M Powell, B. Erickson, L Kuroki, C Cosgrove,
11:15-11:55	Review of studies in development	V Makker, A Fader, A. Secord, A. Klopp, S. Bose
11:55-12:00	Additional discussion / Questions	open

NRG ONCOLOGY

Advancing Research. Improving Lives.™

AGENDA
NRG VA/MTF SUBCOMMITTEE MEETING
Monday, January 13, 2025
12:00 pm – 1:00 pm EST
VIRTUAL

I. Discussion of clinical trials of interest

a. Update on VA accruals
b. Strategic targets for 2025 openings across VHA

NRG NCORP is developing a cancer prevention concept, NRG-CC2342: Phase II randomized, placebo-controlled trial testing the efficacy of broccoli seed and sprout extract (Avmacol Advanced®) in preventing second primary tumors (SPTs) after an index, tobacco-related head and neck squamous cell carcinoma (HNSCC).

II. Strategic challenges

a. Personnel challenges
b. Cross-institutional tissue banking/sharing
c. Regulatory approval- centralization

III. Open discussion

NRG ONCOLOGY

Institutional Accrual

#NRG2025

Accrual For Agenda Book from 7/1/2024 to 12/31/2024 Run Date: 1/8/2025				
NRG Main Member (Network)	CTEP ID	Accrued to NRG Studies and Credited to NRG	Accrued to Non-NRG NCTN Studies and Credited to NRG	Total
Allan Blair Cancer Centre	11076	6	0	6
Allegheny General Hospital	PA009	13	1	14
Arizona Center for Cancer Care-Peoria	AZ127	12	0	12
Arthur J E Child Comprehensive Cancer Centre	11134	3	0	3
Ascension Alexian Brothers - Elk Grove Village	IL280	0	0	0
Aurora NCI Community Oncology Research Program	AURORA	37	32	69
Avera Cancer Institute	SD021	5	10	15
Banner University Medical Center - Tucson	AZ017	11	2	13
Baptist Health Cancer Research Network	BHCRN	6	22	28
Baptist MD Anderson Cancer Center	FL003	3	2	5
Bay Area Tumor Institute NCORP	BATI	0	0	0
Baylor College of Medicine/Dan L Duncan Comprehensive Cancer Center	TX041	2	6	8
Baystate Medical Center	MA004	1	1	2
BCCA-Vancouver Cancer Centre	11081	15	0	15
Berkshire Medical Center - Cancer Center	MA125	0	0	0
Boston Medical Center	MA043	0	7	7
Cancer Research Consortium of West Michigan NCORP	CRCWM	49	2	51
Cancer Research for the Ozarks NCORP	OZARKS	25	0	25
Cancer Research of Wisconsin and Northern Michigan Consortium	CROWN	43	4	47
Cancer Trials Ireland	ICORG	1	0	1
Carle Cancer Center NCI Community Oncology Research Program	CARLE	11	0	11
Carolinas Medical Center/Levine Cancer Institute	NC042	23	0	23
Cedars-Sinai Medical Center	CA016	11	5	16
Centre Hospitalier Universitaire de Sherbrooke-Fleurimont	11065	18	0	18
Chinese University of Hong Kong-Prince of Wales Hospital	34003	0	0	0
CHU de Quebec-L'Hotel-Dieu de Quebec (HDQ)	11073	23	0	23
CHUM - Centre Hospitalier de l'Universite de Montreal	11062	13	0	13
City of Hope Comprehensive Cancer Center	CA043	14	14	28
CIUSSSEMTL-Hopital Maisonneuve-Rosemont	11060	0	0	0
Columbia University Minority Underserved NCORP	COLUMBIA	11	2	13
Columbus NCI Community Oncology Research Program	COLUMBUS	8	4	12
CommonSpirit Health Research Institute	CORA	16	6	22
Community Cancer Center North	IN006	0	0	0
Cooper Hospital University Medical Center	NJ036	13	11	24

Corewell Health William Beaumont University Hospital	MI005	4	9	13
Covenant Medical Center-Lakeside	TX054	0	0	0
Cross Cancer Institute	11132	0	0	0
CWRU Case Comprehensive Cancer Center LAPS	LAPS-OH029	63	2	65
Dana-Farber / Partners CancerCare LAPS	LAPS-MA036	18	2	20
Danbury Hospital	CT030	1	4	5
Dartmouth College - Dartmouth Cancer Center LAPS	LAPS-NH012	29	3	32
Dayton NCI Community Oncology Research Program	DAYTON	0	0	0
Delaware/Christiana Care NCI Community Oncology Research Program	CHRISTIANA	23	0	23
Dell Seton Medical Center at The University of Texas	TX063	2	3	5
Duke University - Duke Cancer Institute LAPS	LAPS-NC010	12	0	12
Edward Hospital/Cancer Center	IL104	12	3	15
Emory University - Winship Cancer Institute LAPS	LAPS-GA005	19	2	21
Essentia Health NCI Community Oncology Research Program	ESSENTIA	6	0	6
Fox Chase Cancer Center	PA086	4	12	16
Fred Hutchinson Cancer Research Center LAPS	LAPS-WA008	7	5	12
Froedtert and the Medical College of Wisconsin LAPS	LAPS-WI013	35	2	37
Geisinger Cancer Institute NCI Community Oncology Research Program	GEISINGER	14	1	15
Georgia Cares Minority Underserved NCORP	GACARES	8	0	8
Georgia NCI Community Oncology Research Program	GEORGIA	17	9	26
Global Oncology Trials Japan	GOTJ	2	0	2
Greater Baltimore Medical Center	MD018	2	0	2
Gulf South Minority Underserved NCORP	GULFSOUTH	23	0	23
Hackensack University Medical Center	NJ022	2	0	2
Hartford Hospital	CT009	2	12	14
Hawaii Minority Underserved NCORP	HAWAII	8	8	16
Heartland Cancer Research NCORP	HEARTLAND	23	0	23
Henry Ford Hospital	MI026	13	4	17
Houston Methodist Hospital	TX036	3	0	3
Indiana University/Melvin and Bren Simon Cancer Center	IN007	18	1	19
Intermountain Medical Center	UT056	13	3	16
Iowa-Wide Oncology Research Coalition NCORP	IWORC	9	5	14
James A. Haley Veterans Affairs Hospital	FL064	0	0	0
Jewish General Hospital	11116	1	0	1
JHU Sidney Kimmel Comprehensive Cancer Center LAPS	LAPS-MD017	13	2	15
Juravinski Cancer Centre at Hamilton Health Sciences	11183	0	0	0
Kaiser Permanente NCI Community Oncology Research Program	KAISER	470	16	486
Kaiser Permanente-Gaithersburg Medical Center	MD198	3	12	15

Kantonsspital Aarau	67029	1	0	1
Lahey Hospital and Medical Center	MA017	4	1	5
Lankenau Medical Center	PA125	0	0	0
Laura and Isaac Perlmutter Cancer Center at NYU Langone	NY011	22	0	22
Legacy Good Samaritan Hospital and Medical Center	OR013	2	1	3
Loyola University Medical Center	IL017	3	0	3
MaineHealth Cancer Care Network	MAINE	11	15	26
Mayo Clinic LAPS	LAPS-MN026	20	4	24
Medical University of South Carolina Minority Underserved NCORP	MUSC	36	4	40
MedStar Franklin Square Medical Center/Weinberg Cancer Institute	MD029	8	4	12
Memorial Sloan-Kettering Cancer Center LAPS	LAPS-NY016	23	1	24
Metro Minnesota Community Oncology Research Consortium	METROMIN	50	0	50
Miami Cancer Institute	FL078	16	3	19
Miami Valley Hospital	OH084	5	9	14
Michigan Cancer Research Consortium NCORP	MCRC	24	0	24
Michigan Healthcare Professionals Farmington	MI310	9	0	9
Michigan State University Clinical Center	MI038	0	0	0
Midwestern Regional Medical Center	IL120	2	0	2
Moffitt Cancer Center	FL065	12	5	17
Montana Cancer Consortium NCORP	MONTANA	6	1	7
Montefiore Minority Underserved NCORP	MONTEFIORE	11	2	13
Mount Sinai Hospital	NY021	20	4	24
MU Health - University Hospital/Ellis Fischel Cancer Center	MO036	9	0	9
National Cancer Centre Singapore	47005	0	0	0
National Institutes of Health Clinical Center	MD004	0	0	0
NCORP of the Carolinas (Prisma Health NCORP)	GREENVILLE	0	8	8
Nebraska Methodist Hospital	NE007	0	7	7
Nevada Cancer Research Foundation NCORP	NCRF	1	4	5
New Mexico Minority Underserved NCORP	NEWMEXICO	27	2	29
New York-Presbyterian/Brooklyn Methodist Hospital	NY075	16	1	17
NorthShore University HealthSystem-Evanston Hospital	IL018	4	2	6
Northwell Health NCORP	NORTHWELL	27	0	27
Northwestern University LAPS	LAPS-IL036	12	1	13
Norton Hospital Pavilion and Medical Campus	KY049	1	0	1
Odette Cancer Centre- Sunnybrook Health Sciences Centre	11118	12	0	12
Ohio State University Comprehensive Cancer Center LAPS	LAPS-OH007	45	5	50
Oklahoma Cancer Specialists and Research Institute-Tulsa	OK037	0	0	0
Orlando Health Cancer Institute	FL020	4	2	6

Ottawa Hospital and Cancer Center-General Campus	11025	2	0	2
Pacific Cancer Research Consortium NCORP	PCRC	23	1	24
Parkview Regional Medical Center	IN181	1	3	4
Penn State Milton S Hershey Medical Center	PA042	11	2	13
Peter MacCallum Cancer Centre	3003	0	0	0
Piedmont Hospital	GA027	1	7	8
ProMedica Flower Hospital	OH012	5	2	7
Puerto Rico Minority Underserved NCORP	PUERTORICO	13	0	13
Reading Hospital	PA107	4	5	9
Rhode Island Hospital	RI005	9	0	9
Riverside Methodist Hospital	OH008	5	0	5
Roswell Park Cancer Institute LAPS	LAPS-NY158	10	1	11
Rush University Medical Center	IL043	5	1	6
Rutgers Cancer Institute of New Jersey	NJ066	24	2	26
Saint Joseph Hospital - Orange	CA087	5	1	6
Saint Joseph's Hospital and Medical Center	AZ009	0	0	0
Sanford NCI Community Oncology Research Program of the North Central Plains	SANFORD	11	3	14
Sarah Cannon Cancer Center	TN047	3	0	3
Saskatoon Cancer Centre	11120	10	0	10
Seoul National University Hospital	43002	5	0	5
Southeast Clinical Oncology Research Consortium NCORP	SCOR	79	0	79
Stanford Cancer Institute Palo Alto	CA141	17	0	17
Stony Brook University Medical Center	NY184	15	25	40
Stroger Hospital of Cook County Minority Underserved NCORP	STROGER	7	1	8
Summa Health System - Akron Campus	OH055	1	5	6
Sun Yat-sen University Cancer Center	60021	0	0	0
Sutter Cancer Research Consortium	SUTTER	1	0	1
The James Graham Brown Cancer Center at University of Louisville	KY002	8	13	21
The Research Institute of the McGill University Health Centre (MUHC)	11318	22	0	22
The US Oncology Network	USONC	0	0	0
Thomas Jefferson University Hospital LAPS	LAPS-PA121	26	7	33
Thompson Cancer Survival Center	TN038	0	0	0
Tibor Rubin VA Medical Center	CA041	0	0	0
Trinity Cancer Care Center	ND026	0	2	2
TROG Cancer Research	TROG	0	0	0
Tulane University School of Medicine	LA001	0	2	2
UC Davis Comprehensive Cancer Center LAPS	LAPS-CA189	13	1	14
UC Irvine Health/Chao Family Comprehensive Cancer Center	CA088	5	0	5
UC San Diego Moores Cancer Center	CA249	18	1	19
UCLA / Jonsson Comprehensive Cancer Center	CA006	29	0	29
UCSF Medical Center-Mount Zion	CA136	8	0	8

UNC Lineberger Comprehensive Cancer Center LAPS	LAPS-NC007	5	1	6
University Health Network-Princess Margaret Hospital	11030	31	0	31
University of Alabama at Birmingham / Deep South Research Consortium LAPS	LAPS-AL002	3	0	3
University of Arkansas for Medical Sciences	AR006	20	0	20
University of Chicago Comprehensive Cancer Center LAPS	LAPS-IL057	10	7	17
University of Cincinnati Cancer Center-UC Medical Center	OH070	4	43	47
University of Colorado Cancer Center LAPS	LAPS-CO070	31	1	32
University of Florida Health Science Center - Gainesville	FL015	9	31	40
University of Illinois	IL040	15	3	18
University of Iowa/Holden Comprehensive Cancer Center	IA018	25	0	25
University of Kansas Cancer Center - MCA Rural MU NCORP	KANSAS	40	3	43
University of Kentucky/Markey Cancer Center	KY010	3	1	4
University of Maryland/Greenebaum Cancer Center	MD015	15	9	24
University of Miami Miller School of Medicine-Sylvester Cancer Center	FL028	29	8	37
University of Michigan Comprehensive Cancer Center LAPS	LAPS-MI014	15	0	15
University of Minnesota/Masonic Cancer Center	MN022	6	6	12
University of Mississippi Medical Center	MS005	0	1	1
University of Nebraska Medical Center	NE003	18	0	18
University of Oklahoma Health Sciences Center LAPS	LAPS-OK003	30	17	47
University of Pennsylvania/Abramson Cancer Center	PA075	10	3	13
University of Rochester LAPS	LAPS-NY167	12	5	17
University of South Alabama Mitchell Cancer Institute	AL068	0	9	9
University of Tennessee - Knoxville	TN021	2	2	4
University of Tennessee Health Science Center	TN030	0	0	0
University of Texas Health Science Center at San Antonio	TX059	7	5	12
University of Texas MD Anderson Cancer Center LAPS	LAPS-TX035	47	0	47
University of Texas Medical Branch	TX045	0	1	1
University of Texas Southwestern Medical Center LAPS	LAPS-TX011	12	0	12
University of Utah - Huntsman Cancer Institute LAPS	LAPS-UT003	7	6	13
University of Vermont and State Agricultural College	VT004	18	0	18
University of Virginia Cancer Center	VA009	9	0	9
University of Wisconsin Carbone Cancer Center LAPS	LAPS-WI020	23	5	28
UPMC Hillman Cancer Center LAPS	LAPS-PA015	82	3	85

Upstate Carolina Consortium Community Oncology Research Program	UPSTATE	25	0	25
USC Norris Comprehensive Cancer Center LAPS	LAPS-CA011	6	7	13
Vanderbilt University - Ingram Cancer Center LAPS	LAPS-TN008	10	1	11
VCU Massey Cancer Center Minority Underserved NCORP	VCU	19	13	32
Veterans Administration Hospital	FL051	24	0	24
Wake Forest University Health Sciences	NC002	8	0	8
Walter Reed National Military Medical Center	MD001	1	0	1
Washington University - Siteman Cancer Center LAPS	LAPS-MO011	48	8	56
Wayne State University - Karmanos Cancer Institute LAPS	LAPS-MI020	24	9	33
WellSpan Health-York Hospital	PA047	16	1	17
West Virginia University Charleston Division	WV004	0	1	1
West Virginia University Healthcare	WV025	1	13	14
Western States Cancer Research NCORP	WESTERN	0	0	0
Wisconsin NCI Community Oncology Research Program	WINCORP	7	0	7
Women and Infants Hospital	RI012	14	5	19
Women's Cancer Center of Nevada	NV049	25	0	25
Yale University - Yale Cancer Center LAPS	LAPS-CT018	51	2	53
Yonsei University Health System-Severance Hospital	43027	0	0	0

NRG2025 Travel Awardees

Congratulations to all of the members who received travel awards to the NRG 2025 Winter Meeting. We look forward to your involvement and contributions!

Rebecca Baca

Edward Bleta

Anne Brooks

Cynthia Dwight

Mark Fischer

Adriana Gamboa

Timothy Guinn

Melissa Hana

Haley Kelly

Rachel Lacy

Brittany Lansford

Erin McDowell

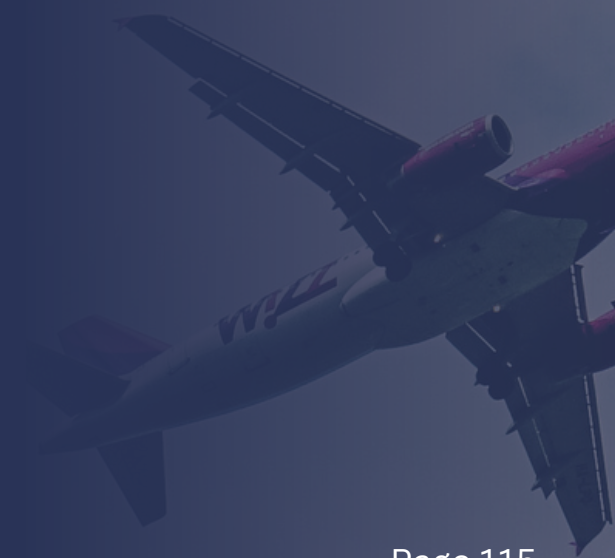
Beryl Lauren Manning-Geist

Cortney Montgomery

Jessica Schnase

Tomás Yokoo Teodoro de Souza

James Tsui



Sponsors & Exhibitors

Platinum Sponsor

AbbVie
AbbVie's mission is to discover and deliver innovative medicines and solutions that address complex health issues and enhance people's lives. Our commitment is measured by the impact we make – to patients, to our communities, and to the world. Our approximately 50,000 employees strive to make a remarkable impact that lasts, driven by our compassion for people, commitment to innovation and inclusion, service to the community and uncompromising integrity. Today our products help more than 60 million people living in more than 175 countries, and we are making significant advancements with a robust pipeline of potential new medicines as we look to find the treatments of tomorrow.

Platinum Sponsor

GSK
GSK is a focused, global biopharma company. Our purpose is to unite science, technology and talent to get ahead of disease together and positivity impact the health of billions of people.

Natera
Signatera is a custom-built circulating tumor DNA (ctDNA) test for molecular residual disease (MRD) assessment and treatment response monitoring in patients previously diagnosed with cancer. Signatera's performance has been clinically validated in multiple solid tumors including colorectal, breast, and bladder cancers as well as for immunotherapy response monitoring.

Foundation Medicine
Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care.

Sponsors & Exhibitors

Verastem
Verastem Oncology is late-stage development biopharmaceutical company committed to the development and commercialization of new medicines to improve the lives of patients diagnosed with cancer. Our pipeline is focused on RAS/MAPK-driven cancers, specifically novel small molecule drugs that inhibit critical signaling pathways in cancer that promote cancer cell survival and tumor growth, including RAF/MEK inhibition and FAK inhibition. For more information, please visit www.verastem.com and follow us on LinkedIn.

Merck
At Merck, our goal is to translate breakthrough science into innovative oncology medicines to help people with cancer. The potential to bring new hope to people with cancer drives our purpose and our commitment. As part of our focus on cancer, Merck is committed to clinical research with one of the largest development programs in the industry across more than 30 tumor types.

Eisai
As the U.S. pharmaceutical subsidiary of Tokyo-based Eisai Co., Ltd., we are a fully integrated pharmaceutical business with discovery, clinical, and marketing capabilities. Our key areas of focus include oncology and neurology (dementia-related diseases and neurodegenerative diseases). To learn more about Eisai Inc., please visit us at www.eisai.com/US and follow us on Twitter and LinkedIn.

AstraZeneca
We are a global, science-led, patient-focused pharmaceutical company. We are dedicated to transforming the future of healthcare by unlocking the power of what science can do for people, society and the planet.

Sponsors & Exhibitors

Caris Life
Caris Life Sciences is the leading molecular science and technology company actively developing and delivering innovative solutions to revolutionize healthcare and improve patient outcomes. With a primary focus on cancer, Caris suite of market-leading molecular profiling offerings assesses DNA, RNA and proteins to reveal a molecular blueprint that helps patients, physicians and researchers better detect, diagnose and treat patients. To learn more, please visit www.CarisLifeSciences.com.

Corcept Therapeutics
Corcept Therapeutics is a commercial-stage pharmaceutical company engaged in the discovery and development of medications to treat severe endocrinologic, oncologic, metabolic and neurologic disorders by modulating the effects of the hormone cortisol. For more than 25 years, Corcept's singular focus on cortisol modulation has led to the discovery of more than 1,000 proprietary selective cortisol modulators that have the potential to deliver improved patient outcomes across a wide range of diseases. In February 2012, the company introduced Korlym® (mifepristone), the first medication approved by the U.S. Food and Drug Administration for the treatment of patients with Cushing's syndrome. Corcept is headquartered in Menlo Park, California. For more information, visit Corcept.com.

IROC
The Imaging and Radiation Oncology Core (IROC) provides integrated radiation oncology and diagnostic imaging quality control programs in support of clinical trials conducted by NRG Oncology and the other Network Groups in the National Clinical Trials Network. IROC staff are here to answer study data submission related radiation therapy and diagnostic imaging questions from investigators or other clinical research professionals.

Exhibit Hall Schedule:
Thursday 7:00am – 6:00pm
Friday 7:00am – 5:30pm
Saturday 7:00am – 12:30pm

Complimentary coffee, tea, and soft drinks will be served in the exhibit area at specified times on each day that exhibits are open.

Come visit Verastem at Table #2

Low-grade serous ovarian cancer is DISTINCT and DIFFERENT

- LGSOC affects younger patients[1,2]
- LGSOC is likely to be resistant to chemotherapy[3]

LEARN MORE

DISTINCT

Learn more about LGSOC at **LetsTalkAboutLGSOC.com/hcp**

REFERENCES: 1. Plaxe SC. Epidemiology of low-grade serous ovarian cancer. *Am J Obstet Gynecol.* 2008;198(4):459.e1-8; discussion 459.e8-9. **2.** Okoye E, Euscher ED, Malpica A. Ovarian low-grade serous carcinoma: a clinicopathologic study of 33 cases with primary surgery performed at a single institution. *Am J Surg Pathol.* 2016;40(5):627-635. **3.** Grabowski JP, Harter P, Heitz F, et al. Operability and chemotherapy responsiveness in advanced low-grade serous ovarian cancer. An analysis of the AGO Study Group meta database. *Gynecol Oncol.* 2016;140:457-462.

VERASTEM ONCOLOGY

NP-US--24-0217 Last Updated 1/25

MIRASOL was a confirmatory, global, multicenter, randomized, open-label, phase 3 study evaluating the efficacy and safety of ELAHERE vs investigator's choice chemotherapy (paclitaxel, PLD, or topotecan) in FRα-positive, platinum-resistant ovarian cancer. Patients received 1–3 lines of prior systemic therapy; prior bevacizumab and PARPi therapy allowed.[2]

INDICATION

ELAHERE is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

IMPORTANT SAFETY INFORMATION

WARNING: OCULAR TOXICITY

- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

WARNINGS and PRECAUTIONS

Drives to: HCP Website (2024 Update)
US-MIRV-2300281 https://www.elaherehcp.com/

Ocular Disorders

ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with ELAHERE. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow up). Ocular adverse reactions led to permanent discontinuation of ELAHERE in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Please see accompanying Brief Summary of Full Prescribing Information, including Boxed WARNING.

The first treatment to show statistically significant improvements in FRα+ platinum-resistant ovarian cancer[1–3]

ELAHERE improved PFS+OS+ORR vs standard single-agent chemotherapy[1,2]

Efficacy endpoint	ELAHERE (n=227)	Standard chemotherapy (n=226)
Progression-free survival[1] HR: 0.65 (95% CI: 0.52, 0.81), *P*<0.0001	**5.6 months** (95% CI: 4.3, 5.9)	**4.0 months** (95% CI: 2.9, 4.5)
Overall survival[1] HR: 0.67 (95% CI: 0.50, 0.88), *P*=0.0046	**16.5 months** (95% CI: 14.5, 24.6)	**12.7 months** (95% CI: 10.9, 14.4)
Overall response rate[1,4] *P*<0.0001	**42%** (n=95/225) (95% CI: 36, 49)	**16%** (n=36/224) (95% CI: 12, 22)
• **Complete response**	**5%** (n=11)	**0%**
• **Partial response**	**37%** (n=84)	**16%** (n=36)
Duration of response[4]	**6.77 months** (95% CI: 5.62, 7.89)	**4.47 months** (95% CI: 4.17, 5.82)

ELAHERE Safety Profile[1]

- Rate of serious AEs: 24% (n=52) with ELAHERE (n=218) vs 33% (n=68) with standard chemotherapy (n=207)[2]
- Rate of discontinuation due to AEs: 9% (n=20) with ELAHERE vs 16% (n=33) with standard chemotherapy[1,2]
- The most common (≥20%) AEs, including laboratory abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils[1]
- 1% of patients treated with ELAHERE reported alopecia (Grade 1) vs 14% of patients treated with standard chemotherapy (7% Grade 1 and 7% Grade 2)[4]
- In the MIRASOL study, the median duration of ELAHERE treatment was 5 months (range: 0.69 to 27.4)[1]

Give your patients the opportunity for
more moments that count with **ELAHERE**
Learn more at **ELAHEREhcp.com**

AE=adverse event; CI=confidence interval; FRα=folate receptor alpha; HR=hazard ratio; ORR=overall response rate; OS=overall survival; PARPi=poly(ADP-ribose) polymerase inhibitor; PFS=progression-free survival; PLD=pegylated liposomal doxorubicin.

References: 1. ELAHERE. Package insert. ImmunoGen, Inc.; 2024. **2.** Moore KN, Angelergues A, Konecny GE, et al. Mirvetuximab soravtansine in FRα-positive, platinum-resistant ovarian cancer. *N Engl J Med*. 2023;389:2162–2174. **3.** Matulonis UA, Lorusso D, Oaknin A, et al. Efficacy and safety of mirvetuximab soravtansine in patients with platinum-resistant ovarian cancer with high folate receptor alpha expression: results from the SORAYA study. *J Clin Oncol*. Published online January 30, 2023. doi:10.1200/JCO.22.01900 **4.** Data on file. ImmunoGen, Inc. Waltham, MA.

immunogen

IMPORTANT SAFETY INFORMATION (CONT'D)

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE.

Pneumonitis occurred in 10% of patients treated with ELAHERE, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology. Pneumonitis led to permanent discontinuation of ELAHERE in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

Peripheral Neuropathy (PN)

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%). Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening PN, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of PN.

Embryo-Fetal Toxicity

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

ADVERSE REACTIONS

The most common (≥20%) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

DRUG INTERACTIONS

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

USE IN SPECIAL POPULATIONS

Lactation

Advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

Hepatic Impairment

Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Please see accompanying Brief Summary of Full Prescribing Information, including Boxed WARNING.

ELAHERE® (mirvetuximab soravtansine-gynx) injection, for intravenous use. Initial U.S. Approval: 2022

WARNING: OCULAR TOXICITY

- **ELAHERE can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.**
- **Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of ELAHERE, every other cycle for the first 8 cycles, and as clinically indicated.**
- **Administer prophylactic artificial tears and ophthalmic topical steroids.**
- **Withhold ELAHERE for ocular toxicities until improvement and resume at the same or reduced dose.**
- **Discontinue ELAHERE for Grade 4 ocular toxicities.**

1 INDICATIONS AND USAGE

ELAHERE® is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

5 WARNINGS AND PRECAUTIONS

5.1 Ocular Disorders

ELAHERE can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with ELAHERE. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow up. Ocular adverse reactions led to permanent discontinuation of ELAHERE in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with ELAHERE are recommended. Advise patients to avoid use of contact lenses during treatment with ELAHERE unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue ELAHERE based on severity and persistence of ocular adverse reactions.

5.2 Pneumonitis

Severe, life-threatening, or fatal interstitial lung disease (ILD), including pneumonitis, can occur in patients treated with ELAHERE.

Pneumonitis occurred in 10% of patients treated with ELAHERE, including 1% with Grade 3 events and 1 patient (0.1%) with a Grade 4 event. One patient (0.1%) died due to respiratory failure in the setting of pneumonitis and lung metastases. One patient (0.1%) died due to respiratory failure of unknown etiology.

Pneumonitis led to permanent discontinuation of ELAHERE in 3% of patients.

Monitor patients for pulmonary signs and symptoms of pneumonitis, which may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded through appropriate investigations. Withhold ELAHERE for patients who develop persistent or recurrent Grade 2 pneumonitis until symptoms resolve to ≤ Grade 1 and consider dose reduction. Permanently discontinue ELAHERE in all patients with Grade 3 or 4 pneumonitis. Patients who are asymptomatic may continue dosing of ELAHERE with close monitoring.

5.3 Peripheral Neuropathy

Peripheral neuropathy occurred in 36% of patients with ovarian cancer treated with ELAHERE across clinical trials; 3% of patients experienced Grade 3 peripheral neuropathy. Peripheral neuropathy adverse reactions included peripheral neuropathy (20%), peripheral sensory neuropathy (9%), paraesthesia (6%), neurotoxicity (3%), hypoaesthesia (1%), peripheral motor neuropathy (0.9%), polyneuropathy (0.3%), and peripheral sensorimotor neuropathy (0.1%).

The median time to onset of peripheral neuropathy was 5.9 weeks (range 0.1 to 126.7). Of the patients who experienced peripheral neuropathy, 23% had complete resolution and 12% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade) at last follow up. Peripheral neuropathy led to discontinuation of ELAHERE in 0.7% of patients.

Monitor patients for signs and symptoms of neuropathy, such as paresthesia, tingling or a burning sensation, neuropathic pain, muscle weakness, or dysesthesia. For patients experiencing new or worsening peripheral neuropathy, withhold dosage, dose reduce, or permanently discontinue ELAHERE based on the severity of peripheral neuropathy.

5.4 Embryo-Fetal Toxicity

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Ocular Disorders.
- Pneumonitis.
- Peripheral Neuropathy.

6.1 Clinical Trials Experience

The pooled safety population described in Warnings and Precautions reflect exposure to ELAHERE in 682 patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer at 6 mg/kg AIBW administered intravenously once every 3 weeks until disease progression or unacceptable toxicity in Study 0416, Study 0417, Study 0403 (NCT02631876), and Study 0401 (NCT01609556). The median duration of treatment was 4.4 months (range: 1.0 to 30.0). In the pooled safety population, the most common (≥20%) adverse reactions, including laboratory abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Study 0416

The safety of ELAHERE was evaluated in Study 0416, a multicenter, open-label, active-controlled, randomized, two-arm, study in patients (n=453) with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer. Patients received ELAHERE 6 mg/kg AIBW once every 3 weeks until disease progression or unacceptable toxicity. The median duration of treatment was 5 months (range: 0.69 to 27.4).

Serious adverse reactions occurred in 24% of patients treated with ELAHERE. The most common (≥2%) serious adverse reactions were intestinal obstruction (5%), abdominal pain (3%), and pleural effusion (3%).

Fatal adverse reactions occurred in 3% of patients, including intestinal obstruction, dyspnea in the setting of subileus, neutropenic sepsis, cardiopulmonary failure, respiratory failure, ischemic stroke, and pulmonary embolus.

Permanent discontinuation of ELAHERE due to adverse reactions occurred in 9% of patients. The most common (≥1%) adverse reactions leading to permanent discontinuation were pneumonitis (2%), blurred vision (1%), and peripheral neuropathy (1%).

Dosage delays of ELAHERE due to an adverse reaction occurred in 54% of patients treated with ELAHERE. Adverse reactions which required dosage delays in ≥3% of patients included blurred vision (22%), keratopathy (19%), dry eye (7%), neutropenia (6%), pneumonitis (6%), photophobia (5%), cataract (4%), and peripheral neuropathy (4%).

Dose reductions of ELAHERE due to an adverse reaction occurred in 34% of patients. Adverse reactions which required dose reductions in ≥3% of patients included blurred vision (14%), keratopathy (10%), peripheral neuropathy (6%), and dry eye (5%).

Tables 4 and 5 summarize adverse reactions and laboratory abnormalities, respectively, occurring in ≥10% of patients who received ELAHERE in Study 0416.

Table 4: Adverse Reactions Occurring in ≥10% of Patients with Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Who Received ELAHERE in Study 0416

Adverse Reaction	ELAHERE (n=218)		Chemotherapy¥ (n=207)	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Gastrointestinal disorders				
Abdominal pain*	34	3	23	2
Diarrhea	29	1	17	0.5
Constipation	27	0	19	1
Nausea	27	2	29	2
Vomiting	18	3	18	1
Eye disorders				
Blurred vision°	45	9	3	0
Keratopathy†	37	11	0	0
Dry eye‡	29	3	5	0
Photophobia	18	0.5	0.5	0
Cataract^	16	3	0.5	0
General disorders and administration site conditions				
Fatigue¥	47	3	41	7
Nervous system disorders				
Peripheral neuropathy¶	37	4	23	4
Headache	14	0	10	0
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain◊	31	1	21	2
Metabolism and nutrition disorders				
Decreased appetite	18	1	14	1
Respiratory, thoracic, and mediastinal disorders				
Pneumonitis±	10	0.5	0.5	0

¥Chemotherapy: paclitaxel, pegylated liposomal doxorubicin (PLD), topotecan.
°Blurred vision includes vision blurred, vitreous floaters, visual acuity reduced, diplopia, accommodation disorder, and visual impairment.
†Keratopathy includes corneal disorder, corneal epithelial microcysts, keratitis, keratopathy, corneal deposits, punctate keratitis, and corneal opacity.
‡Dry eye includes dry eye and lacrimation increased.
^Cataract includes cataract and cataract nuclear.
¥Fatigue includes fatigue and asthenia.
*Abdominal pain includes abdominal pain, abdominal pain upper, abdominal pain lower, and abdominal discomfort.
¶Peripheral neuropathy includes neuropathy peripheral, peripheral sensory neuropathy, peripheral motor neuropathy, paresthesia, hypoesthesia, polyneuropathy, neurotoxicity, and peripheral sensorimotor neuropathy.
◊Musculoskeletal pain includes back pain, myalgia, neck pain, arthralgia, musculoskeletal pain, non-cardiac chest pain, bone pain, pain in extremity, musculoskeletal stiffness, musculoskeletal chest pain, and musculoskeletal discomfort.
±Pneumonitis includes pneumonitis, interstitial lung disease, respiratory failure, and organizing pneumonia.

Clinically relevant adverse reactions occurring in <10% of patients who received ELAHERE in Study 0416 included infusion related reactions/ hypersensitivity (8%).

Table 5: Select Laboratory Abnormalities ≥10% for All Grades, in Patients Who Received ELAHERE in Study 0416

Laboratory Abnormality	ELAHERE (n=218)		Chemotherapy (n=207)	
	All Grades (%)	Grades 3-4 (%)	All Grades (%)	Grades 3-4 (%)
Liver Function Tests				
Increased aspartate aminotransferase	57	0	14	0
Increased alanine aminotransferase	38	1	15	1
Increased alkaline phosphatase	30	1	13	1
Chemistry				
Decreased albumin	21	1	27	2
Decreased magnesium	21	1	29	2
Decreased sodium	16	0	18	0
Decreased potassium	15	1	11	1
Increased calcium	12	0	5	0
Decreased bicarbonate	11	0	11	0
Increased creatinine	10	0	11	0
Hematology*				
Decreased lymphocytes	27	3	42	11
Decreased leukocytes	23	1	53	10
Decreased neutrophils	22	1	45	17
Decreased hemoglobin	18	1	63	8
Decreased platelets	17	1	20	5

*The denominator used to calculate the rate varied from 63 to 214 (ELAHERE); 63 to 194 (IC Chemo) based on the number of patients with a baseline value and at least one post-treatment value.

Immunogenicity: Anti-Drug Antibody-Associated Adverse Reactions

In studies 0416, 0417, 0401, and 0403 in patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer who received ELAHERE at 6 mg/kg AIBW administered intravenously once every 3 weeks, 9% (57/626) developed anti-drug antibodies. Infusion reactions (including bronchospasm, erythema, eyelid erythema, flushing, hypersensitivity, periorbital edema, rash, allergic rhinitis, face edema) occurred in 26% (15/57) of patients with anti-drug antibodies and in 7% (41/569) who did not develop anti-drug antibodies.

7 DRUG INTERACTIONS

7.1 Effects of Other Drugs on ELAHERE

Strong CYP3A4 Inhibitors

DM4 is a CYP3A4 substrate. Concomitant use of ELAHERE with strong CYP3A4 inhibitors may increase unconjugated DM4 exposure, which may increase the risk of ELAHERE adverse reactions. Closely monitor patients for adverse reactions with ELAHERE when used concomitantly with strong CYP3A4 inhibitors.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, ELAHERE can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (DM4) and affects actively dividing cells. Human immunoglobulin G (IgG) is known to cross the placental barrier; therefore, ELAHERE has the potential to be transmitted from the mother to the developing fetus. There are no available human data on ELAHERE use in pregnant women to inform a drug-associated risk. No reproductive or developmental animal toxicity studies were conducted with mirvetuximab soravtansine-gynx. Advise patients of the potential risk to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data: No reproductive or developmental animal toxicity studies have been conducted with mirvetuximab soravtansine-gynx. The cytotoxic component of ELAHERE, DM4, disrupts microtubule function, is genotoxic, and can be toxic to actively dividing cells, suggesting it has the potential to cause embryotoxicity and teratogenicity.

8.2 Lactation

Risk Summary

There are no data on the presence of mirvetuximab soravtansine-gynx in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

8.3 Females and Males of Reproductive Potential

ELAHERE can cause embryo-fetal harm when administered to a pregnant woman.

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating ELAHERE.

Contraception

Females: Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

8.4 Pediatric Use

Safety and effectiveness of ELAHERE have not been established in pediatric patients.

8.5 Geriatric Use

Of the 682 patients with epithelial ovarian cancer who were treated with ELAHERE across studies, 44% of patients were ≥65 years old. Grade ≥3 adverse reactions occurred in 51% of patients ≥65 years and in 45% <65 years. No clinically meaningful differences in efficacy or safety were observed between patients ≥65 years of age compared to younger patients.

Age does not have a clinically meaningful effect on the pharmacokinetics of ELAHERE.

8.6 Renal Impairment

No dosage adjustment of ELAHERE is recommended for patients with mild to moderate renal impairment (CLcr 30 to 89 mL/min). The effect of severe renal impairment (CLcr 15 to < 30 mL/min) or end-stage renal disease on ELAHERE is unknown.

8.7 Hepatic Impairment

Avoid use of ELAHERE in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

No dosage adjustment of ELAHERE is recommended for patients with mild hepatic impairment (total bilirubin ≤ULN and AST >ULN or total bilirubin >1 to 1.5 times ULN and any AST).

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Ocular Disorders

Inform patients about the need for eye exams before and during treatment with ELAHERE.

Advise patients to contact their healthcare provider promptly if they experience any visual changes. Advise patients to use steroid eye drops and artificial tear substitutes.

Pneumonitis

Advise patients to immediately report new or worsening respiratory symptoms.

Embryo-Fetal Toxicity

Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients to inform their healthcare provider of a known or suspected pregnancy.

Advise females of reproductive potential to use effective contraception during treatment with ELAHERE and for 7 months after the last dose.

Lactation

Advise women not to breastfeed during treatment with ELAHERE and for 1 month after the last dose.

Manufactured by:
ImmunoGen, Inc.
Waltham, MA 02451
1-781-895-0600
U.S. License 2288
US-MIRV-2300442

NRG Oncology
2025 WINTER MEETING
PHOENIX, AZ

Thank You

NRG Oncology would like to thank and acknowledge the following companies for providing Independent Medical Education (IME) grant support associated with the 2025 Winter Semiannual Meeting of NRG Oncology.

ABBVIE

EXACT SCIENCES

ELI LILLY

PFIZER

SIEMENS/VARIAN MEDICAL SYSTEMS

NRG ONCOLOGY

Future Meeting Dates & Locations

July 24-26, 2025 - Washington D.C.

Jan. 22-24, 2026 - San Francisco, CA

July 16-18, 2026 - Denver, CO